EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO

IN RE DAVOL, INC./	)MDL Docket No.
C.R. BARD, INC.	)2846
POLYPROPYLENE HERNIA MESH	)
PRODUCT LIABILITY LITIGATION	)
LITIGATION, MDL 2817	)
	)
THIS DOCUMENT RELATES TO:	)
JESUS CAMPOS	)Case No. 2:18-cv-00915
STEVEN JOHNS	)Case No. 2:18-cv-01509
THOMAS McCOURT	)Case No. 2:18-cv-01011
ANTONIO MILANESH	)Case No. 2:18-cv-01320
GREGORY MILLER	)Case No. 2:18-cv-01443
AARON STINSON	)Case No. 2:18-cv-01022
	)

Videotaped Deposition of David A. Kessler, M.D.
Washington, D.C.
January 31, 2020
8:03 a.m.

Reported by: Bonnie L. Russo

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Videotaped Deposition of David A. Kessler, M.D.
held at:

Cohen, Milstein, Sellers & Toll, PLLC
1100 New York Avenue, N.W.
Washington, D.C.

Pursuant to Notice, when were present on behalf of the respective parties:

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PROCEEDINGS

(Deposition Exhibit 1 was marked for identification.)
(Deposition Exhibit 2 was marked for identification.)
(Deposition Exhibit 3 was marked for identification.)
(Deposition Exhibit 4 was marked for identification.)
(Deposition Exhibit 5 was marked for identification.)

THE VIDEOGRAPHER: Good morning. We are going on the record at 8:03 a.m. on January 31st, 2020. Please note that the microphones are sensitive and may pick up whispering, private conversations and cellular interference. Please turn off all cell phones or place them away from the microphones as they can interfere with the deposition audio. Audio and video recording will continue to take place unless all parties agree to go off the record.

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This is Media Unit 1 of the video-recorded deposition of Dr. David A. Kessler, taken by counsel for Defendant in the matter of In Re Davol, Incorporated\C.R. Bard, Incorporated, Polypropylene Hernia Mesh Product Liability Litigation, filed in the United States District Court for the Southern Division of Ohio, Docket No. MDL 2846.

This deposition is being held at Cohen Milstein Sellers & Toll, PLLC, located at 1100 New York Avenue, Northwest, Washington, D.C.

My name is Daniel Russo from the firm Veritext Legal Solutions. The court reporter is Bonnie Russo from the firm Veritext Legal Solutions.

Counsel and all present in the room will now state their appearances and affiliations for the record, please.

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MS. STOKES: Kelsey Stokes for the plaintiffs and the PSC.

MS. AMINOLROAYA: Parvin Aminolroaya for the plaintiffs.

MR. McWILLIAMS: Ned McWilliams, Levin Papantonio, for the plaintiffs.

MR. JESSEE: Sean Jessee for defendants C.R. Bard and Davol.

MR. FOSTER: James Foster for defendants C.R. Bard and Davol.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

DAVID A. KESSLER, M.D.,
was called for examination by counsel and, after having been duly sworn by the Notary, was examined and testified as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT

BY MR. JESSEE:

Q. Good morning, Doctor.
A. Good morning, sir.

Q. We just met a few minutes ago. But just to reintroduce myself, my name's Sean Jessee. And I represent the defendants Bard and Davol in this case.
And I might say "Bard," and you know I'm referring to both Bard and Davol, correct?
A. Of course.
Q. And I know you've been deposed a number of times before so I won't go over the rules. Just two things I wanted to point out.
If you need a break at any time, just let me know. I'm happy to accommodate.
A. You're very kind.
Q. And if at any point when -- and I'm sure it'll happen -- if I ask a question that you don't understand, if you could please just let me know. I'll try to ask a better question. If you don't say anything, I'll assume that you understood the question I'm asking.
Does that sound fair enough?
A. Fine. Perfect.

Q. To try to move things along here today, I went ahead and marked several documents that I had previously been provided as exhibits just so we can get this out of the way for the record.
The Exhibit 1 is the deposition notice that was served in connection with your deposition. And that's something it looks like you brought with you as well.
A. I brought a copy, sir.
Q. Okay. So I take it that is something you received?
A. Yes, sir.
Q. Exhibit No. 2 is the expert report that you served -- or that was served on us in this litigation. It's dated December 4th, 2019. And we'll just put this over here.
I understand that you've also brought your own version of the report?
A. I did.
Q. And it's nicely bound there, it looks like, and probably a lot easier to find

what you need to.
Is this the same version that's before -- that you have before you that was served on December 4th, 2019?
A. Correct.
Q. And I see there's -- do you have the different -- the way it's organized, it look like, do you have it by the schedules and the appendixes --
A. Correct.
Q. -- bound in there?
Very good.
Exhibit No. 3 was a document that was provided to us yesterday by your counsel. And this is a supplemental reliance list dated January 30, 2020.
So I'm going to put this over here for you. And we'll talk about that here a little later.
Exhibit No. 4 was another document that was provided to us by your counsel yesterday. This is titled "Errata Sheet for

the 12-4-2019 Expert Report of David A. Kessler, MD."
And then Exhibit No. 5 is an invoice that was provided to us today dated December 10th, 2019, in the amount of $237,264.93.
So I'll just put these all over here.
And, Doctor, I can see that you brought a number of documents with you today. And so I just want to briefly walk through those, what you brought with you.
So if you could, please, sir, just starting with what's right in front of you.
A. So I have a number of sheets in front of me, number of sheets behind me. These are just cut and paste. These are notes over time. Happy to have you look at them.
So there are sheets. There are different size sheets. There's small sheets; there's larger sheets; and there's even larger sheets. And they're all behind me.
Q. Okay. Well, what I'm going to do is

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mark these as an exhibit.
And we can see if these are-- are these your working copy?
A. Yes.
Q. Okay. Then we can see about maybe making a copy of them. I'm fine if we make -- if we can make a copy at the break, using those as -- as an exhibit, and letting you keep your original copies.
But I'm going to go ahead and mark these as Exhibit No. 6, the documents you brought here.
And so we will put it on this -- I see you have a -- is that an index there that says "General" on the top of it?
A. There's an index to the sheets.
MR. JESSEE: Okay. So I'm going to go ahead and mark that -- that index as Exhibit No. 6.
(Deposition Exhibit 6 was marked for identification.)
THE WITNESS: Sure. My only request

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is to -- so that I have these available. You may have to make special arrangement. They're sort of large. The -- somehow you'll -- maybe after you'll arrange with counsel to have them copied.
MR. JESSEE: Absolutely.
THE WITNESS: Just -- they're not -- they're -- they're just not going to fit into a normal copy machine.
MR. JESSEE: Sure. I'll tell you what. We'll work it out. I'll work it out with your counsel after -- or during a break. But just want to make sure it's clear for the record.
BY MR. JESSEE:
Q. And so these documents, these large sheets that you have with you, you -- you said "cut and paste."
And are these cut and paste from your report?
A. They may be cut and paste from my report. You know, these are schedules. For

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example, in front of me, the cut and paste, they may be cut and paste from just documents that are cited in my report. They may be my report. They -- they may be documents that are cited in my report, for example.
So they're -- but they're almost everything -- I don't want to say "everything," but I -- they should be things that you produced or in my report.
So -- and there may be notes on some of these stuff, obviously.
Q. How did you decide which parts to -- either parts of your report or documents to cut out and put in -- paste in these documents you brought with you today?
A. There -- it's a period -- it's over time. It's what's salient in some ways at that moment in time. And there is no -- just -- you would have to track the neural synapsis in my brain firing at any given moment why certain things were salient and why I said, "I'm going to cut this out and put this down."

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But it's -- you know, it's what -- there are a lot of documents in this case. I've had access to the entire database. I've searched the entire database. But you know there's a lot of documents in there.
And so this -- there's just a lot of paper. And some of this may be more salient than other things.
Q. Okay. It's things thought at some point in time at least you thought were salient?
A. Oh, it could have been, yeah, for some reason, or things I just -- it's -- it's hard to keep every fact in your head, every number in your head. That's impossible. There are a lot of devices in this case. So there -- I think you -- you -- you articulated well.
Q. And can you just walk me through -- I see you have a number of different of these large sheets put together. This one in front of you right now, it says "General."
And what -- what does that indicate

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when it says "General"?
A. So general, for example, this has all -- this has, for example, five devices. I may have sets of sheets that are specific to one device, right? So this is general across the devices, right?
Others may be labeled a collection or Ventralight ST or Ventralex or PerFix Plug that I may pull in front of me, you know, on a specific device.
I don't want to -- these are all cut and paste. These are all sloppy. This is not meant for, you know, prime time but just -- these are just, again, different things that it cited or saw, I mean, at different points in time in working on this case.
Q. And just -- so these other large documents -- and I haven't had a chance to look at these yet though.
But are these the ones that are right behind you on the table?
A. Yes, sir.

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Q. And then there's a number -- I see binders too.
Are those your counsel's, or are those things that you brought?
A. No. Those are mine.
Q. Those are things you brought too.
If you wouldn't mind, could you just walk me through each of these sets of documents and binders, and just tell me what they are?
A. You -- how specific do you want me to get? Do you want --
Q. Just, I think, a general overview. And I'll let you know if I need any more specificity.
A. Great.
May I turn around?
Q. Please.
A. So as I said, you'll see that there are sets of sheets on different topics, right?
Q. Okay.
A. So there's a set of sheets -- may I stand?

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Q. Yeah. You don't need to ask permission from me at all, Doctor.
A. That's fine.
So, for example, you'll see there are sets of sheets. This is general because it's multiple devices. You see a set of sheets on 3DMax, on Quintiles, on large Ventralex, on material safety data sheet, on PerFix Plugs.
So you have a number of sheets on different subjects.
Q. Okay.
A. Okay?
Q. All right. Thank you, Doctor.
And then -- so I see then there are -- it looks like there's some --
A. Larger sheets.
Q. Larger sheets. Okay.
And what -- why -- what are on those?
A. Those are just -- those are -- those larger sheets couldn't be printed out. I think they're -- they're Excel spreadsheets. They

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just need -- in order to be readable, they had to be larger.
Q. Oh.
A. And so they are primarily a listing of studies or animal studies or preclinical studies on different devices. So that's what those are. And those are spreadsheets of those things.
Q. Okay. Is there anything in these sheets that you've brought with you that is not in your report?
A. Perhaps.
Q. Okay. And would -- would it be fine be with you at the next break if we just take a look at those so I can determine if there are any questions --
A. Sure --
Q. -- to ask about it?
A. If you could just leave them intact so I can use them and refer to them, I'm happy to have you look and make copies of them. They're certainly all available for you to

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review.
Q. Okay. Thank you very much.
Doctor, I want to talk a little bit about your background and qualifications.
And you actually have a section in your report titled "Qualifications," correct?
A. Correct.
Q. And that's in your report on Page No. 1. And --
MS. STOKES: Can you give me a copy of this, all the exhibits.
THE WITNESS: Here. I can give you -- if you -- oh.
MS. STOKES: I think he owes me some.
Thank you.
MR. JESSEE: Uh-huh.
Then the invoice he has just provided, I don't -- I just have two --
MS. STOKES: That's fine.
MR. JESSEE: I just received two copies.

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BY MR. JESSEE:
Q. So, Dr. Kessler, obviously you're a medical doctor, correct?
A. Correct.
Q. And your background is in pediatrics?
A. Correct.
Q. And you did your internship and residency both in pediatrics?
A. Correct.
Q. And I understand that at one time you were board certified in pediatrics, but you no longer are?
A. Correct.
Q. And --
A. I'm board -- I mean I'm -- I am still board eligible. I just -- I mean I -- I let it go. I mean I -- I just didn't do my recertification. I can -- I'm eligible to do that as soon as I can get time. If you let me out from here.
Q. Sure. And I understand --

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A. I'm -- I'm happy to do that.
Q. It's a voluntary decision.
A. That's correct.
Q. The -- when was the last time you treated patients in a hospital setting?
A. In a hospital setting? Actually in the hospital is the question.
Q. In the hospital. Yes, sir.
A. Oh, probably -- I don't know -- early 2010. Don't hold me to exactly. 20 teens is my guess.
Q. Okay. And do you regularly see patients either in a hospital or office setting at --
A. I see --
Q. -- currently?
A. I -- I see patients but not in their hospital setting. And I don't have a traditional office. But I take care of patients all of the time.
Q. Okay. And when you say you don't have a traditional office, then where would you

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typically see a patient?
A. I will see a patient where I could see a patient. Some of this is on the phone. Mostly I -- you know, I mean I probably spent two, three hours a day on -- don't want to overstate it every day -- but taking care of patients at one sort or another.
Q. And I understand, as part of your medical training, you have -- be involved with and learn about surgery when you're back in -- doing your residency during your internship, correct?
A. So I certainly did a lot of pediatric surge -- I was the one pediatrician who was assigned -- I was the only one who could deal with the surgeons. So I was sort of assigned to pediatric surgery division. So I did a good deal of surgery.
Q. Okay. Today though you don't represent yourself as a surgeon.
A. So --
Q. Is that fair?

A. So as my California license -- I mean I think -- says -- it says "a licensed physician" -- "physician and surgeon." But I think that's somewhat anachronistic.

So in the State of California, you're licensed as a physician and surgeon. But you wouldn't want me taking care of you in the operating room, I think would be fair.

Q. Okay. And for purposes of this litigation, your role in this litigation's not as a surgeon; is that -- is that fair?

A. So I think where my role in this litigation, I probably have great expertise certainly on the regulation of surgical products. That I have great expertise.

So any medical device that would involve surgeons or as it -- so it's that interface between surgery and that product and that regulation and that framework for regulation that I probably have the -- the most expertise on.

Q. Okay. But not as far as actually

implanting the device; you're not the person who's going to actually go and implant a hernia mesh device, correct?

A. You do not want me to do that.

Q. When was the last time that you performed a surgery?

A. You have to -- not to be -- quibble with you, sir. You have to define "surgery." The last time took out a splinter. So there's a -- there's a range of -- of surgical procedures.

Is a bone marrow a surgical procedure? It -- it depends what you mean by "surgical procedure."

Q. Okay. When was the last time that you implanted a medical device into a patient?

A. I don't think -- I mean I worked in a division of surgical research, but it was -- it would be decades ago where I was in the operating room.

So you would, again -- that -- again, my expertise is on the regulation of

implantable devices. I certainly can watch tapes and understand that -- those aspects as it relates to the regulation.

But I don't go -- you let the surgeons talk about the practicalities of what happens in the OR. But on the regulation and the use, I would have expertise.

Q. And do you know if you've ever implanted a permanent medical device in a patient?

MS. STOKES: Object to form.

Go ahead.

THE WITNESS: I'd have to go -- we'd have to go back and look at -- I mean I would not have done that alone. I think it would be fair. I think that would be improper.

I may have been in the OR with a implantable device. I may have done that in -- in animal models when I was in surgical research. But I have no recollection, sitting here, of doing that in recent years.

Q. Okay. Would it be fair to say, if

it did happen, it was back during your residency or internship?

A. I mean I was also medical director of a -- may have been -- a medical director of a hospital for a decade. So I may have been in the OR.

But again, I -- that's not -- I -- I don't actually do the implantation.

Q. And so I take it that you've -- you've never yourself implanted a hernia mesh in a patient?

A. I think that would be a correct statement.

Q. Have you been in the OR when a hernia mesh was implanted in a patient?

A. I have no recollection, sir, of that.

Q. Okay. Is it -- it's possible, though, that you have been; is that fair?

A. It certainly is possible. I just don't have a recollection, sir. It would be decades ago.

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Q. In addition to doing your medical training, you also went to law school, correct?
A. Correct.
Q. And as I understand it, you -- while you graduated from law school, obtained your JD, you didn't actually take -- ever take the bar to become a lawyer, right?
A. I -- I did that deliberately. I resisted.
Q. Smart move, I'd say.
But you -- you don't hold yourself out to be a lawyer, right?
A. I don't hold myself -- I've been a -- I've taught at Columbia Law School. I've published law review articles. I certainly have engaged in that kind of scholarship. You know, I've had articles -- articles that I've written in law review journals have been cited before the court.
But I don't hold myself out as a lawyer. I'm not licensed deliberately.
Q. What is your current occupation?

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A. So I'm a physician.
Q. Okay. In your position, I also understand that you're a professor of pediatrics and epidemiology and biostatistics at the University of California at San Francisco?
A. Correct.
Q. And that's a institution that you've been at for quite a while now?
A. 2003.
Q. Okay. And you serve -- you were the dean there --
A. Correct.
Q. -- for a time period. And then you've served as -- you've had this -- positions as professors.
And when I say the professor of pediatrics, is that separate then from professor of epidemiology and biostatistics?
A. They're -- they're different departments and divisions.
Q. Do you have an office at UCSF?

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A. I had. But there's some seismic issue with the office. So I had to give it up for seis -- for earthquake reasons. But happy to go into those.
Q. No. We can probably, I think, skip that -- that -- that part of it.
A. Right.
Q. I want to talk a little bit about your time as commissioner of the FDA. And I understand that the -- that was from 1990 to 1997.
Can you give me a little more within that -- exactly -- do you know the start and end dates during that time period?
A. Start is a little complicated. Depends on your view of constitutional law, on date of confirm, on date of oath, I mean.
But generally view December 1990 to, I believe, the end of February '97.
Q. And that was the -- that time when you served as commissioner, that was the only time during your career that you were an

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employee at the FDA, correct?
A. Correct.
Q. And you're not here speaking on behalf of the FDA, obviously, right?
A. Absolutely. You could underline that, put an asterisk. I'm speaking here, you know, just my own -- on my own. I don't represent the FDA.
I certainly have the experience of a former FDA commissioner. I could tell you what I would do -- how things would be pertinent for me if I were FDA commissioner. You know, have 40 years of experience, probably more, in FDA regulation. But I do not speak for FDA.
Q. Okay. Right.
And you -- and you said you can say what you would have done if you were commissioner, but that's going to be your opinion, not the FDA's official opinion, right?
A. That's correct. I mean the F -- the FDA -- there may be documents that we can look at where we can objectively determine what

FDA's opinion would have been. And I certainly could tell you what FDA's opinion was when I was there.

Q. Right.

And you're not though going to be testifying about the FDA or an individual FDA employee's state of mind, correct?

A. I wouldn't rep -- want to talk about anyone's state of mind, the FDA's employees' or anyone else's. I think that would be improper.

Q. Okay. That would be -- and that would include Bard or Bard employees?

A. I -- I -- nothing on subjective intent.

Q. Now, as commissioner, you -- obviously you oversaw the entire FDA operation, right?

A. I was commissioner of the FDA.

Q. Yeah.

And that involved -- and I think you have it here in your report -- that there were five different divisions at that time when you

were commissioner?

A. We can count them. I know foods, drugs, medical devices, animal drugs, center for veterinary -- I'm sorry -- National Center For Toxicological Research and Center For Biologics.

So depending on how you count, it's five or six, whether you include NCTR or not.

Q. Okay. And it -- actually there's another issue sort of outside of those five or six areas that took up a large amount of your time when you were commissioner, right?

MS. STOKES: Objection. Form.

THE WITNESS: Be -- be a little more specific.

BY MR. JESSEE:

Q. Okay. What -- what would you say was the biggest controversy when you were -- during your time as commissioner --

MS. STOKES: Objection. Form.

BY MR. JESSEE:

Q. -- of the FDA?

MS. STOKES: Form.

THE WITNESS: I -- I -- it depends on who you ask, I think.

BY MR. JESSEE:

Q. Okay. And I'm just going from some of your prior testimony.

But do you have -- in your personal opinion, what was the -- one of the biggest controversies you had when you were --

A. Well, I mean, again, let --

MS. STOKES: Objection. Form. Vague.

THE WITNESS: But -- but let me see if I can help you --

MR. JESSEE: Sure.

THE WITNESS: -- I mean, and go through it.

I mean if you were with HI -- if you had HI -- if you were a patient with HIV, you would say, during that period of time, HIV was the most important, the most controversial issue.

If you're a person of the -- from the food industry, you may say the food label was the most important thing that we did, the nutrition facts.

If you're a person from medical devices, you may say it was breast implants or our push to increase the scientific underpinnings of devices and move toward improved clinical trials.

I think what you're probably getting at is the -- the regulation of cigarette -- nicotine as a drug, right, which would have been done under the drug authority. So it -- it does have a place in FDA.

And that probably is probably the most well known and may have, depending on where you sit, I mean, as great an impact as anything else.

BY MR. JESSEE:

Q. And I think you -- you made a good point in -- in clarifying my question.

There was actually -- there was a

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lot of very important things that happened at the FDA in a number of different areas when you were commissioner there, correct?
A. Correct.
MS. STOKES: Objection. Form.
THE WITNESS: Correct. I mean -- but -- as there always is.
BY MR. JESSEE:
Q. Oh, sure. And I'm not -- yeah. I'm not trying to suggests -- I mean -- and when you say it always is, it's not just when you were commissioner there.
There's been a lot of important things that the FDA has done in these different areas throughout the last 25 years and plus, right?
A. Correct.
MS. STOKES: Objection. Form.
THE WITNESS: I'm sure you'll -- at one point you'll -- you'll have a question and ask me whether it's the most important consumer protection agency in the world, and I will say

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yes.
BY MR. JESSEE:
Q. Okay. Well, maybe we can just skip that question now.
The -- I was looking online at the FDA web site. And they're -- they have numbers for the total number of full-time employees there for the last few years.
And the numbers that I saw from 2016 to 2018 were between -- each year was between 15,000 and 17,000 full-time employees.
Does that sound about right to you?
A. Correct.
Q. How many full-time FDA employees were there when you were commissioner?
And I know it's been a while. But if you could just give me best estimate.
A. 10,000.
Q. You mentioned in some of the -- in your listing just some of the important accomplishments.
And I -- I would take it those

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were -- certainly weren't all the important accomplishments that occurred while you were at FDA, right?
MS. STOKES: Objection. Form.
THE WITNESS: There were a lot of things that -- that went on. I mean there were -- I mean we did -- for example, I cite here, you know, the quality system, regulations and devices.
MR. JESSEE: Right.
THE WITNESS: And there are -- there are many things that we can talk about.
BY MR. JESSEE:
Q. Sure. And that -- my only point -- I mean I didn't want to shortchange you. And I am not trying to make it sound like that was all you did, but --
A. You're -- you're kind. I mean it -- I think you can -- it was an active period. I was a pretty hands-on commissioner.
Q. One of the -- when you were talking about some of those important actions that

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occurred while you were commissioner, you mentioned a push to increase scientific underpinnings of medical devices.
Can you tell me a little more what you mean by that?
A. You could go -- I mean go read, for example, the -- what's basically known as The Temple Report. So we -- I think -- the device -- the device center, device -- what was passed in '76 and then reenacted in 1990 -- not reenacted, sorry, but amended -- it was primarily a grata to Bureau of Radiological Health.
And it was primarily viewed and staffed by engineers. Nothing wrong with engineers. I mean we need engineers. And they'd looked at the mechanical properties of devices. And they were not as focused on the clinical consequences of devices.
So we -- but there was a great deal of push to improve the clinical evaluation of medical devices. The -- the industry pushed

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back. I think -- I mean Alan Magazine, who -- I mean when I -- the day I left, he handed me a coffee cup that had my picture on it with a circle and a line through that he had on his desk.

Because, you know, we tried to increase the -- the -- the scientific underpinnings of how devices should be tested in people. The industry should have -- the -- the clinical -- the -- the -- the clinical data, especially when you're dealing with devices that impact cert -- health and that are implantable.

Q. And, in fact, one of the accomplishments I think you list in your report is you created the committee for clinical review?

A. That would be the Temple Committee.

Q. Okay. And this Temple Report that you're referring to, that's something I'm not familiar with.

What is that exactly?

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A. So The Temple -- The Temple Report basically looked at studies that the CDRH device center had been doing and said the quality of those devices were relatively poor; they were not adequate and well controlled; didn't have defined end points.

They -- they -- there -- there was not the kind of testing that the agency had grown up and had pioneered for drugs to assure the safety on drugs. And it was basically to improve the scientific quality of device studies.

Q. Okay. Then that would, in -- in turn, have a positive impact on patient safety and health, correct?

MS. STOKES: Objection. Form.

THE WITNESS: Yes. That was the goal.

BY MR. JESSEE:

Q. Another -- trying to think of the best term to use here -- I guess accomplishment or another thing that happened with regard to

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medical devices during your time as commissioner was the MedWatch program was established?

MS. STOKES: Objection. Form.

BY MR. JESSEE:

Q. Is that correct?

A. Correct.

Q. And could you -- that was a -- a program that involved the tracking of adverse events that are happening in medical devices?

A. So -- fair.

Q. And maybe man -- maybe I should expand that, say also the mandatory reporting?

MS. STOKES: Objection. Form.

THE WITNESS: Yes and no. So the MedWatch really was to encourage voluntary reporting. It -- it -- it grew up certainly with -- you know, the -- the largest tradition was in drugs but did include all device -- all products: foods, biologics, devices.

It was try -- it was a recognition that voluntary reporting is notoriously

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underreported. And manufacturers have to report -- there are -- I mean, in certain instances, there are defined requirements. And then there were -- users had a -- user facilities had a report. There were certain defined requirements.

But for the vast majority of individuals, reporting was voluntary. They didn't know. And if you said, you know, there's -- the device complication rate is .04 percent, and that's what we get, and that's notoriously underreported.

We don't know the exact something -- I mean somebody once said there was the Kessler rule. It's really not -- it wasn't me. But there's -- it was an effort to increase reporting, I think was the --

BY MR. JESSEE:

Q. Okay. And again, in -- we'll -- we'll talk a little bit more about medical device reports later.

But again, the real goal of the

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MedWatch program though is to help improve the safety of these different product -- products that you're regulating, right?
MS. STOKES: Objection. Form.
THE WITNESS: So it was to gather information in a post-marketing environment.
BY MR. JESSEE:
Q. And the goal of that gathering of that information was to improve the consumer and patient safety, correct?
MS. STOKES: Objection. Form.
THE WITNESS: As all FDA action does. It was another -- it was another set of data.
BY MR. JESSEE:
Q. You mention in your report in Paragraph 5 that you placed a high priority on getting promising therapies for serious and life threatening diseases to patients as quickly as possible.
And can you tell me what you mean by that sentence?

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A. Sure. When I became FDA commissioner in 1990, there was one drug for HIV on the market. People were dying. It didn't work very well.
By the time left in 1997, we had enacted the accelerated approval regulations. And there were -- I don't know the exact number. There were some 17 drugs -- so the effort of a lot of people. I don't want to take credit there -- but some 17 drugs for HIV.
And that changed the course. It wasn't a -- was not a cure but went from a -- pretty much a death sentence to something that at least there was a -- a good chance of meaningful life --
Q. Okay. So --
A. -- with those drugs.
Q. And I apologize. I didn't mean to interrupt you there, Doctor.
But the -- so, in general, the -- the purpose of the -- of that was to -- in layperson's terms, I guess, you want to --

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there are certain drugs that you need a faster approval process than others, that these are drugs that patients need to be able the get --
MS. STOKES: Objection.
BY MR. JESSEE:
Q. -- faster.
MS. STOKES: Objection. Form.
THE WITNESS: I think way to say -- there are certain conditions for serious and life threatening conditions where there are not alternative therapies, right? You -- there's no other -- you're dying, and there's not an alternative therapy.
So you can put certain forms of cancer in there. And you can put some neurodegenerative diseases in there, diseases where there's a real dire need for new therapies.
BY MR. JESSEE:
Q. Well, and you also implemented measures that offer all drugs to be reviewed faster for -- procedures for that to take place

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as well, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Little -- there's some nuances in the way you phrased the questions. I don't mean to be -- I think you're probably get to the Prescription Drug User Fee Act.
Reviewed faster but hopefully as thoroughly, right? I just -- I just want to do that. But we did the prescription drug user fee that had defined performance goals for the agencies.
But in return the agency got more resources in order to hire more people. So you can get more done in shorter periods of time.
BY MR. JESSEE:
Q. Right.
And I -- and so it's just as thorough of a -- of a review. But with the fee that the manufacturer or whoever is submitting it pays, then you're able to have more resource -- resources review it quicker; is that --
MS. STOKES: Objection. Objection.

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Form.
THE WITNESS: The -- the -- we would hope that what you just said happens in all instances. But it's complicated all the time.
BY MR. JESSEE:
Q. Okay. And actually, after the time you were commissioner, there was a medical device user fee system similar to what you had implemented for the drugs that was put in place, correct?
MS. STOKES: Objection. Form.
THE WITNESS: As there was a generic drug user fee. There were a number of users fees that followed in those -- that kind of model.
BY MR. JESSEE:
Q. Okay. And those, again, allow for more resources for -- the review time may be shorter, but it doesn't necessarily mean that the -- it's not as thorough, the review that's under -- being undertaken, right?
MS. STOKES: Objection. Form.

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THE WITNESS: Depends on the -- depends on the review. And again, there's complexities to that statement.
BY MR. JESSEE:
Q. Okay. And the -- you would agree that, as a general proposition, that just -- that the review time isn't necessarily indicative of how thoroughly a product is being reviewed?
MS. STOKES: Objection. Form. Assume facts.
THE WITNESS: I wouldn't agree with that.
BY MR. JESSEE:
Q. Okay. So --
A. I mean I'm happy -- happy to explain why. I don't mean to be --
Q. No. That's fine. We'll -- I'll tell you what. We'll come back to that.
Let's talk a little bit about -- well, let me withdraw that and try it again.
Do you agree that, during your time as commissioner, the FDA played a crucial role in ensuring the safety and well-being of people all over the country?

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MS. STOKES: Objection. Form.
THE WITNESS: You mean -- are you quoting me?
BY MR. JESSEE:
Q. I just want to know if you agree with it, Doctor. I'm not --
A. I mean if you have a --
Q. I'm not trying to trick you or anything like that.
A. If you -- if --
MS. STOKES: Same objection.
THE WITNESS: If you have a foundation for the statement.
BY MR. JESSEE:
Q. No. I -- No. I just want to know if you agree with it. I'm...
A. It's one of those general statements that are -- that's made. Again, there's multiple aspects to that.

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Q. Okay. I mean and I understand, it's a general statement that's made, like you said.
Is that though something that you agree with?
MS. STOKES: Objection. Form.
THE WITNESS: Well, let's get the exact -- just give me the exact quote again.
Q. Sure.
Would you agree that the FDA plays a crucial role in ensuring the safety and well-being of people all over the country?
MS. STOKES: Objection. Form.
THE WITNESS: As -- sure, in general, right? But not in every single product class.
So if you're talking about a NDA -- I'm sorry. If you're talking new drug application, I mean the FDA has thoroughly reviewed. If you're talking about a dietary supplement where you don't have FDA review, in essence, you -- that statement would not apply.
If you're talking about a PMA, that

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would apply, you know, to some extent depending on what manufacturer -- so if you have a 510(k), you have less so.

So -- so you just have to be careful about generalities as what it applies to. I mean where -- I mean FDA's only as good as the authority gets -- has under the statute and is only as good as the information the manufacturer has.

But there should be no doubt that it's the manufacturer that has primary responsibility to assure the safety of its products.

BY MR. JESSEE:

Q. Would you agree that your -- it was your experience, when you were at the FDA, that the FDA employees are full of dedicated professionals who share a commitment to protect and enhance the public health?

A. Yeah.

MS. STOKES: Objection. Form.

THE WITNESS: I would ask, if you're

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quoting me, just to let me know.

BY MR. JESSEE:

Q. And as far as I -- you know, I -- I can't tell you if I'm quoting you or not.

A. Well, it sounds like you're quoting me.

Q. Well, and so that sounds like something you would say?

A. It -- it --

MS. STOKES: Objection. Form.

THE WITNESS: -- it sounds like I'm -- and if you have a foundation, just -- can you be up -- I just appreciate if you'd be -- let me know if you're quoting me.

BY MR. JESSEE:

Q. I -- I -- I will. I'll tell you I -- I can't tell you -- I -- I honestly do not know if I'm quoting you or not. I've -- I've certainly though seen statements similar to that in your prior testimony. I can't tell you if that's exact words or not.

A. Right. So -- so let -- so again, I

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-- I will assume that, if you're quoting me, you'll let me know you're quoting me, just as a foundation.

I think that it's fair to say -- I mean those are the kinds of things that -- and I -- I have enormous respect for people at the agency. But it's, as you know, 10,000 people. There are people who could out tomorrow and earn five, ten times what their salary. Some of them I've said publicly are national resources. Others are clunkers.

I mean so -- I mean it's like any large organization. Does FDA get everything right? Absolutely not. But I think, in general, it's an agency that is a very important -- I have enormous respect for.

Q. Okay. And certainly -- and I completely understand what you're saying. With a large organization like that, you're not -- you'll, you know, get a variety of different people working there at different levels.

But you certainly, as commissioner,

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try to put competent and thorough people in charge, in supervisory positions, right?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. I think that's a generalization that -- I mean to name the position -- I mean let's be specific. If you want to name a person in a position, I'll tell you whether I think they're competent.

I don't want to make a general -- I mean a statement that everybody is competent that was put in in -- in a general statement. So just -- if you could be --

BY MR. JESSEE:

Q. Well --

A. -- a little more --

Q. Well, let's go with -- I mean --

A. -- focused in your question.

Q. Which actually -- what levels of physicians were you personally involved with making -- with hiring or choosing who's going to serve in that position?

MS. STOKES: Objection. Form.

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THE WITNESS: I -- I -- there -- we'd probably have to spend the rest of the deposition I mean to go through --

BY MR. JESSEE:

Q. Oh. That's fair. That's fair.

A. I mean that kind of -- so there are -- there are positions that reported to me, right, that obviously I mean I would have been involved in. There were center directors that I was involved in -- in naming.

But there were -- you take the promotional branch. I was involved in -- again, not -- you know, sort of as a team. I don't want to -- I never tried to usurp, and was very careful, the person's supervisor.

But I would at times play at a number of different layers of the organization. So, for example, on drug promotion, I was -- I was hands-on or promotional activities. Or in compliance, for example, in devices I may have had some say.

Q. Well, let's focus on devices.

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The -- the -- the division that regulated back then and now medical devices is the Center For Devices and Radiological Health or CDRH?

A. The center. Yes, sir.

Q. And that's the -- there is a -- within the CDRH a office of device evaluation, correct?

A. These come by different names over -- over times. But there is -- there are -- there's a device evaluation center divisions, yes.

Q. Okay. That division, whether it's the device evaluation -- the office of device evaluation or another name though, that's the division that's responsible for reviewing medical devices before they go to the market.

Is that a fair statement?

MS. STOKES: Objection. Form.

THE WITNESS: Depending on the statutory -- it depends on the statutory structure of what they're responsible for.

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So again, the -- the -- there are certain exempt devices that they would not be responsible for, I mean because they don't have authority. But, you know, again, it depends on what -- the class of devices we're talking about.

BY MR. JESSEE:

Q. Sure.

But for the majority of medical devices that are going to market, those are going to be reviewed by the Office of Device Evaluation?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. I -- I -- I don't mean to be -- to quibble. But even your -- the -- the word "review," right? I mean what does "review" mean? There's review for substantial equivalence. There's review for safety and effectiveness.

It becomes complicated because the device -- there's different types of devices.

BY MR. JESSEE:

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Q. Well, and absolutely. And we're going to talk -- I promise you we'll talk at length about a 510(k) process and a PMA.

But you're not testifying that -- under either process there's still review of the application or the PMA, right?

MS. STOKES: Objection. Form.

BY MR. JESSEE:

Q. There's -- we can talk about -- we'll talk about the -- how in-depth it is.

But as far as -- you're not suggesting that there's not a review at all, are you?

MS. STOKES: Objection. Form.

THE WITNESS: Well, in certain exempt devices. I mean certain Class I devices there's not --

MR. JESSEE: Right.

THE WITNESS: -- a review.

BY MR. JESSEE:

Q. But for Class II devices that are subject to the 510(k) or Class III that are

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subject to the PMA, there -- the FDA reviews and they apply different standards, but they're gong to review both those submissions, right?
MS. STOKES: Objection. Form.
THE WITNESS: So there -- there's a notification. It's -- there's a notification. And depending on who you ask what the terminology is, some may use the word "concurrence," others -- I mean so what the exact terminology is on the 510(k).
BY MR. JESSEE:
Q. Okay. And when you say "concurrence" though, that would be akin to saying clearance, correct?
A. Correct.
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. And though -- again, just -- so my question though is, with regard to whether there's a review by the FDA of 510(k) applications.
We can review there is a review --

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we can agree there's a review, right?
MS. STOKES: Objection. Form.
THE WITNESS: There is -- let's -- I think it would be -- if you added that -- so for clarity, there is a review for substantial equivalence to see whether the device can be cleared. But there's not an approve -- a review for approval based on safety and effectiveness.
BY MR. JESSEE:
Q. Sure. And there's -- there's primary reviewers though for 510(k) applications that come in, correct?
MS. STOKES: Objection. Form.
THE WITNESS: I mean there -- there are certain people assigned to applications.
BY MR. JESSEE:
Q. And those are typically engineers or scientists?
MS. STOKES: Objection. Form.
THE WITNESS: Not -- it depends.
BY MR. JESSEE:

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Q. Okay. What does it depend on?
A. It depends on the -- the branch, the staffing, the type of device that comes in. So it depends how the -- the nature of the device.
Q. Okay. There's a number of different branches within the CDRH, right, with -- that cover different types of devices?
MS. STOKES: Objection. Form.
THE WITNESS: Correct.
BY MR. JESSEE:
Q. And depending on what the -- and speaking about 510(k)s now, depending on what type of products involved, that will determine which branch is going to receive the application, correct?
A. Correct. And at different points in times those branches have gotten reorganized and...
Q. Sure.
And when we talk about the -- there's generally a primary reviewer assigned for 510Kk) applications?

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Is that your experience?
MS. STOKES: Objection. Form.
THE WITNESS: There'll be a -- generally there'll be a person assigned, yes.
BY MR. JESSEE:
Q. Okay. But there's actually multiple layers of review, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Depends. Depends on the application. There could be. I mean everyone has a supervisor.
BY MR. JESSEE:
Q. Sure.
And so they might go up to their supervisor and ask questions within their division or even within the CDRH, right?
MS. STOKES: Objection.
THE WITNESS: Or to me. I mean I -- I would get questions from -- I mean on the complicated -- on complicated devices they will ask me.
BY MR. JESSEE:

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Q. Okay. For 510(k)s?
A. I have to go -- some of the more controversial may have been 510(k) that I -- that I certainly played on.
Q. I'll tell you what. I'll -- we'll -- I'll -- this is a quote that I found from you that says -- when talking about review -- FDA reviewers: "When they didn't know the answer on a clearance or on a device question, it was brought to me. And that was pretty consistent. I mean I would say there wasn't a month that would go by there wasn't a device question, device briefing where I was brought questions."
Is that an accurate...
MS. STOKES: Objection.
THE WITNESS: That's a general statement. I don't -- I think I would probably -- I don't think there would be -- did I say every month? I think that would be fair. I would -- I would -- there would be a device question probably much more often than that.

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And some were -- had all different legal statuses where I was brought questions.
BY MR. JESSEE:
Q. Was there ever a time when you would actually review a 510(k) submission?
MS. STOKES: Objection. Improper hypothetical.
Go ahead.
BY MR. JESSEE:
Q. And -- and by that, let me -- let me rephrase that just so I'm being a little clearer here.
Obviously you were never the primary reviewer for a 510(k) submission, correct?
A. Somebody would -- I mean somebody would usually bring me the question. I think that would be fair.
Q. Okay.
A. I mean -- and again, I was brought the -- the difficult questions.
Q. Okay. So if they have -- if they -- a reviewer is looking at a 510(k), there are --

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maybe a question that their supervisor or their supervisor can't answer where -- someone within the CDRH can't answer, then there were certain difficult questions that would make their way up to you?
MS. STOKES: Objection. Form.
THE WITNESS: I think they want -- you know, pretty collegial. Things that might have had policy implications; things that were in the press. There were major device issues that were in the press, things that would be the subject of congressional hearings. Other kinds of controversies would certainly work their way up to me.
And they would have different regulatory statuses, some 510(k)s, some preamendments, some PMAs, some radiological health. So they were across the board.
BY MR. JESSEE:
Q. And you'd agree that the vast majority of devices that went to marketed when you were commissioner went to the market

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through the 510(k) regulatory pathway, correct?
MS. STOKES: Objection. Form. Vague.
THE WITNESS: I think that's a fair statement.
BY MR. JESSEE:
Q. Did you ever -- during your time as FDA commissioner, still focusing on -- on that time, did you ever review the labeling for a Class II device that was going through the clearance process?
MS. STOKES: Objection. Form.
THE WITNESS: Sure. I mean in the kind of questions -- I mean the labeling is sometimes the intended use. Sometimes the -- the safety, the warnings, the restricted use.
I'd have to go back and think which classes -- which devices were which classes. I don't have those quite in my head.
But certainly what would be say -- what was said about a device was sometimes the key issue. The labeling was key to the

agency's consideration of the device.
BY MR. JESSEE:
Q. Do you recall any specific 510(k)s that you were consulted with while you were the commissioner?
MS. STOKES: Objection. Form.
THE WITNESS: We'd have to go back and look at the regulatory -- the issues that -- but there were a whole bunch of collagen, other type of devices that I were involved in.
Some were -- there were certain implants that were Class II at certain periods of time, then were Class III or down-classed to Class II. So there were -- there were certainly certain sets of implants that's were Class II. Some were Class III. And I just don't have a perfect memory.
But I -- there were cert -- I don't have a memory of exactly which ones were Class II and which ones were Class III. And sometimes they changed classes. And that's

what we did.
Q. Sure. And I -- and I understand this is 25 years ago, approximately. So I understand it's a while ago.
Do you recall ever being consulted with on a surgical mesh 510(k) while you were --
A. Surgical mesh?
Q. Yes.
A. I have no recollection. I guess there were three surgical meshes from your client during that period of time, if my memory -- if I'm right.
I guess it was Visilex or the original Kugel. I think it was right -- '96. I don't recall being involved in any of them.
Q. It's -- is it possible that you were and just don't recall?
MS. STOKES: Objection. Form.
THE WITNESS: I have no recollection. I mean I -- I would tend -- I would -- I would tend to recommend -- I would

tend to remember the name of the device or the type of product. The -- the -- I may not remember the -- I don't remember the classes and all the legal. But I would tend to -- and I do not have any recollection of being involved in any of the surgical mesh devices.
I -- I don't think there were any of the preamendment devices. And most of the devices I were involved in were -- were preamendment devices that were Class III.
MR. JESSEE: Okay. And just to maybe help out here, what I -- I'm going to mark as Exhibit No. 7 a document that we put together from the FDA web site.
(Deposition Exhibit 7 was marked for identification.)
BY MR. JESSEE:
Q. And, Dr. Kessler, you understand obviously that there is a -- you can search the different 510(k)s that have been cleared by the FDA on the web site, right?
A. Correct.

Q. And so what -- what we did in the document that's before you is just go through from the years 1990 to 1997 and searched for the product code for surgical mesh, FTL. And this is just a list of what came up on this search.
MS. STOKES: I'm just going to object to this document generally as foundation.
Go ahead.
THE WITNESS: Yeah. I -- I -- I understand the document.
MR. JESSEE: Okay.
THE WITNESS: And I -- I --
BY MR. JESSEE:
Q. And in --
A. I -- I take the document to be what it is.
Q. Right.
And as far as I mean the number, you can see there's 51 surgical meshes there.
Do you have any reason to dispute

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that 51 surgical meshes were cleared during your time as commissioner?
MS. STOKES: Objection. Form.
THE WITNESS: I -- again, I wouldn't want to rely on this for the exact number. I mean you -- you can -- the record can show what the record shows.
MR. JESSEE: Okay.
THE WITNESS: I think there were three Bard -- let's see -- just see.
How many Bard were there?
BY MR. JESSEE:
Q. Well, why don't we walk through in here what we have here.
A. I mean -- I mean -- so I think there were three Bard devices, if my memory serves me right.
Q. Okay. And when you say if your memory serves you right, are you talking about your memory from the time as commissioner or your memory as part of the litigation work here?

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MS. STOKES: Objection.
THE WITNESS: Part of the -- just total memory, right? Because I don't remember being involved in any mesh device --
MR. JESSEE: Okay.
THE WITNESS: -- issues.
BY MR. JESSEE:
Q. And when we're talking about the specific Bard surgical meshes that were cleared while you were commissioner, we -- if you look at the list we have here, in -- August 24th, 1992, we have the Bard Marlex Mesh Dart?
A. Correct.
Q. And do you recall being consulted on that 510(k)?
A. I was not, to the best of my knowledge.
Q. We also have listed here -- if you'll go to -- the Visilex that I think you talked about?
A. Correct.
Q. And that would have been in 1995?

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A. Correct.
Q. And do you recall being consulted on that 510(k)?
A. I have no recollection. I do not believe I was.
And you should have the Kugel -- the original Kugel should be here.
Q. Okay. And that -- that actually wasn't a Bard product when it was originally cleared, correct?
A. You know -- well, actually, here it is. So you're right. So here it's a -- it's a -- I'm not going to pronounce it right -- a Douglas Bueshel. That -- that device was cleared. That's the third one. It -- it ultimately became Bard.
Q. Do you know when the Kugel line was acquired by Bard?
MS. STOKES: Objection. Form.
THE WITNESS: I do not.
BY MR. JESSEE:
Q. Another one of the devices that's

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listed on this list a number of times, different types of it, is the Gore-Tex device.
Is that a device you're familiar with?
MS. STOKES: Objection. Form.
THE WITNESS: I am certainly familiar with it. No, I do not believe I was -- I was not involved with it. It's an ePTFE. It was not a composite. It was just two layers of ePTFE.
BY MR. JESSEE:
Q. If we look again at the -- towards the end of this list I have in front of you, there is one that's listed in August 6, 1997, Bard Composite Prothesis.
Do you see that?
A. Yeah. It's after I left.
Q. And that's what I was going to try to get. Do you remember exactly or -- when you left?
A. I actually do.
Q. When would that be, Doctor?

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A. It was the last day -- actually, I can remember -- it was a White House ceremony. Off the record, I will tell you why I remember it, but if I -- if I'm correct, it was the last day of February '97.

So that device I did was not involved. I mean, I wasn't involved in any of those, but that was not during my watch.

Q. Right.

A. I mean -- and I think that's key, because that is the -- that is the -- that was the composites, correct?

Q. So what I'm looking at, actually, is the one -- part of the composite?

A. Right. And that is the Marlex Plus. That was based on a Marlex -- the predicates of Marlex Plus ePTFE in '97 in August, right? And so that was a -- that was a different type of device.

Q. And so the -- who was the -- let me strike that and try better.

Was Jim Benson the director of the

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CDRH when you first began?

A. I believe so. He was also deputy commissioner. I think that's correct.

Q. And then I think Dr. Bruce Burlington was the -- in charge of the CDR -- excuse me -- CDRH for a period of time during your --

MS. STOKES: Objection. Form.

THE WITNESS: Correct.

BY MR. JESSEE:

Q. And who was in charge when you left, do you recall?

MS. STOKES: Objection. Form.

THE WITNESS: I don't know whether Dave Feigal was in charge or not. I'm blocking them. I'd have to go back and check.

BY MR. JESSEE:

Q. And you're talking about David -- Dr. David Feigal?

A. Yeah. So Feigal was HIV. I believe he moved over at a certain point. Just don't hold me to it. Bruce, I remember. I

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appointed --

Q. With regard -- and I'll just lump them together. Dr. Benson -- is it Dr. Benson?

A. He was an engineer.

Q. Okay. So Mr. Benson, Dr. Burlington, and Dr. Feigal, I take it you don't have any criticisms of their fulfillment of their duties at the FDA?

MS. STOKES: Objection. Form. Vague. Argumentative. Compound.

Go ahead.

THE WITNESS: Yeah. So that's -- I mean, I'm happy to discuss each one.

You can see in the shift, Jim, very dedicated FDA official for 30 years, was an engineer.

And then you see, as we talked earlier, moving Bruce -- Bruce was in the Center for Drugs. And moving Bruce over to devices was, again, part of that effort to try to improve the science base so it was not just

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engineering, but the clinical science. That was one of the goals.

BY MR. JESSEE:

Q. Okay. And, obviously, you want -- these are devices, a lot of times, that are going to be used by doctors. So you want a more clinical input?

MS. STOKES: Objection. Form. Assumes facts.

THE WITNESS: These are devices that -- you have to understand, when the act was enacted in '76, all implantables were classified as Class III.

I mean, the real answer is not what -- they're going to be used by doctors. They're going to be put in the human body, and they're there permanently.

And, in some ways, drugs are easy, right? You take a drug. I take it for two weeks. It has a half-life of 6 hours to 12 hours. It's in. It's out. It's gone. It has its effect. An implantable is there for the

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duration.

BY MR. JESSEE:

Q. Sure. And part of what you did while you were commissioner was move doctors over from the drug division to the device division so they could be consulted with on submissions that come in, right?

MS. STOKES: Objection. Form.

THE WITNESS: The real goal was not just consultation. The real goal was trying, right? I mean -- and this has been an effort over the last -- I mean, to the point of the Institute of Medicine, I guess, Sheila Burke, right, the criticism of the 510(k) process?

It didn't have that kind of clinical -- the clinical studies, for the most part, the vast majority, are not there.

BY MR. JESSEE:

Q. Right. I'm focusing on the reviewers though. In fact, in some of the 510Ks you reviewed as part of this case, you understand that they -- a physician was brought

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in to consult on in their view of the 510(k), right?

MS. STOKES: Objection. Form. Assumes facts.

THE WITNESS: Well, I'm a physician. So some of the views that I was done -- I'm a physician, right? I mean, so, obviously, Dr. Burlington, Susan Alpert, these were physicians.

That was relatively new during my tenure and done deliberately.

BY MR. JESSEE:

Q. And I was actually focusing on the hernia mesh products that we are talking about here in your report.

You understand that -- and, with regard to the hernia, there are four products that you discuss in your report -- that there were physicians who were brought in in connection with those reviews?

MS. STOKES: Objection. Form.

THE WITNESS: But I -- because

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there's so many, if you could hand me the 510(k), we can determine that by who signed the 510(k). I just don't remember that.

BY MR. JESSEE:

Q. We'll go through it.

And, just as we're sitting here right now, do you recall if any physicians were brought in?

MS. STOKES: Objection. Form.

THE WITNESS: I'd have to go back and see. I mean, I have the 510Ks, and I'm happy to pull them up. And I can tell you in a couple of minutes, if you'd like, who signed what and who was brought in. I just don't have that sitting here. I'm happy to get you the answer.

BY MR. JESSEE:

Q. No. That's fair. I'll show it to you. We can walk through those here in a little bit.

A. Correct.

Q. And, Doctor, I want to ask you

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another -- I'll, again, give you the heads-up. This is -- I'm quoting from your prior testimony that said: "But the 510(k) process was, you know, being used, certainly, when I was commissioner for the vast majority of the devices. And I was being asked questions about those devices and their labels all the time."

Is that a true and accurate statement?

MS. STOKES: Objection. Form. Foundation.

THE WITNESS: Again, all the time? You know, I -- obviously, I was asked about other questions some of the time. So it can't be all the -- it depends on what you mean by all the time. I was doing some other stuff all the time.

So, I mean, again, if you mean pretty often, yes, over the seven years. It was a pretty common event. I don't want to say that I was doing it every moment of every day.

BY MR. JESSEE:

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Q. Fair.
And do you have any specific recollection of mesh devices being cleared or approved while you were commissioner?
MS. STOKES: Objection. Form.
THE WITNESS: The mesh devices I have -- I mean, I look at this list, and I -- I mean, during my tenure, I don't have any recollection sitting here. None of this -- again, we probably have to formally check with exec sec to see whether there is any -- what is called a golden rod or something, some document that passed my desk, but these were not the devices that I recall being involved.
BY MR. JESSEE:
Q. Okay. And I completely understand what you are saying, that it's possible there was one document. I'm just wanting to know what your recollection is.
A. These do not rise to the level of congressional or public scrutiny in between the six or plus years that I was there.

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Q. Okay. And when you say the congressional or public scrutiny, do you recall, at any point during your time as commissioner, anyone voicing concerns to you about hernia mesh products specifically?
MS. STOKES: Objection. Form.
THE WITNESS: That's what I mean. I do not -- I mean, there were other devices that certainly did fall into that. You could go Goggle, you know -- I guess, 1990's, we may not have much of a Google record into that record, right?
There may be some, but if you did silicon breast implants, you'd find a lot. There was a lot of congressional and public involvement.
So you can -- this was a complicated question that the center had, or there was something -- there was some concern that was being picked up that -- and these devices were not of that nature, to the best of my knowledge, in -- from 1990 to -- they were

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relatively straightforward devices, right?
They weren't complicated devices that started even by '97, right, putting together of -- or putting polypropylene in the abdominal cavity, right, intraperitoneally?
Those things were not done. They were relatively simple mesh devices, to my knowledge, I mean, in general.
BY MR. JESSEE:
Q. And, Doctor, I'm looking back now at your report. I know we have been going -- talking about your time at the FDA, and I want to focus just for a few minutes on the time after you left the FDA.
And, specifically looking at the -- in your qualifications section of your report, you talk about your -- in Paragraph 7 is where I am looking, in case you want to check it out.
You talk about you're a senior advisor at TPG Capital, a leading global private equity firm that owns pharmaceutical and biomedical companies?

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A. Correct.
Q. And that's a position you've held for, I believe, quite a while?
MS. STOKES: Objection. Form.
THE WITNESS: Don't hold me -- something -- 2010 or something like that approximately.
BY MR. JESSEE:
Q. And as a senior advisor, do you have an ownership interest in the TPG Capital?
A. No.
Q. You listed a number of companies that you've served on the board of as well?
A. Correct.
Q. And I believe that for -- let me strike that and go through.
The ones you list is -- and please correct me if I'm butchering the names, but Aptalis Pharma?
A. Aptalis.
Q. Aptalis? And that's a pharmaceutical company?

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A. That was. It was acquired.
Q. Okay. And Tokai Pharmaceuticals?
A. Also merged, a pharmaceutical of prostate cancer.
Q. Stoke Therapeutics? Is that a -- what kind of company is that?
A. It was a very early stage -- I was only on the board for a short period of time. It was a sort of gene recombinant therapy, early stage company, more scientific.
Q. And then you also have listed here Immucor, Inc. And that's a medical device and biologics company?
A. It's a blood banking reagent. It's a company that does testing for blood safety and transplants.
Q. And that's actually a company, I know, that's right where -- around where I'm from, Atlanta. It's right around there is where they're based, right?
A. Norcross.
Q. One of the suburbs.

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And the -- is that the only medical device company that you've served on the board of?
MS. STOKES: Objection.
THE WITNESS: Correct.
BY MR. JESSEE:
Q. Okay. When I --
A. Yes. I think that's correct.
Q. All right. And when I say medical device company, obviously, they sort of go into a little bit of that.
A. This --
Q. And maybe you can explain it better to me. I wouldn't consider them a traditional medical device company.
Would that be fair?
MS. STOKES: Objection. Form.
THE WITNESS: Well -- so their equipment is medical devices, but their reagents are biologics.
BY MR. JESSEE:
Q. And how long have you been on the

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board at Immucor?
A. The problem is, I don't know exactly. It's possible. Five, six years. I don't remember exactly.
Q. Okay. And you note in your report here that you have advised companies on the standards and duties of care within the pharmaceutical and medical device industry.
Do you see that?
A. I do.
Q. So when we are talking specifically about the medical device industry and advising companies, would that be at Immucor?
A. Sure.
Q. Any other companies?
A. There may have been other device companies. Nothing, just sitting here, comes to mind, but at TPG, there may have been other questions that have come to me.
Q. Okay. And --
A. In fact, I know there have been other questions that have come to me on

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radiologic -- I mean, on other devices. As I sit here, my mind starts connecting, yes. There have been other -- other device companies.
Q. Would that be more a situation where it might be a specific question, where they come and seek your input on?
MS. STOKES: Objection.
THE WITNESS: Set of questions, yes.
BY MR. JESSEE:
Q. And TPG Capital actually has a number that it owns or --
A. A lot of companies. I mean, there are many -- I mean, I am only involved in the companies, I mean, at a very select basis. I mean, there are some $60 billion, I think under investment. Don't hold me exactly to that.
So there is a broad range of companies, but I am not involved across the board.
Q. Right. And there's a number of different companies. Is it, typically, smaller

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medical device and biologics companies, or is it just all over the map?
MS. STOKES: Objection. Form.
THE WITNESS: Please ask your question. Is what smaller? The ones that TPG owns? The ones I'm involved in?
BY MR. JESSEE:
Q. The ones that TPG owns.
MS. STOKES: Same objection.
THE WITNESS: So, I mean, if you think about it, by its very nature, even though $60 billion sounds -- is a lot of money -- sorry -- you know, a Pfizer that has a worth of 60, whatever it is, it is not going to be able to buy the kind of companies that -- you know, the very big, very large companies.
So I think -- you know, I am involved in TPG Capital. You may have a company that is worth hundreds of millions of dollars. Maybe there is a billion dollar company plus, but it's not going to be tens of billions of dollars.

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BY MR. JESSEE:
Q. When you -- since we were just looking at it a minute ago or since I have advised companies on the standards of duty of care within the pharmaceutical and medical device industry, when we are talking about the -- let's focus on the medical device industry.
When you are advising Immucor on the standards and duties of care for the medical device industry, certainly, a part of that is what the FDA requires, FDA regulations and standards, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Yes.
BY MR. JESSEE:
Q. And, in fact, in this next sentence, you note that you're -- you chaired the compliance committee -- or excuse me.
Going to the second part of that sentence, you note: "I chair the quality committee of Immucor, which involves ensuring

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compliance with the FDA laws and requirements"?
A. Correct.
Q. Can you just tell me a little bit about that position as the quality committee?
A. Sure. I want to be careful that -- I just want to be careful here, because counsel for Immucor is not here. So let's -- I'll give you a general sense.
Q. Yeah. And I'll stop you. I don't want to know any specifics about any specific products or anything that's not publicly available. Just more a general sense of what your duties are.
A. So, again, when one takes over ownership of a company, one picks up -- you know, there are complexities of a company prior.
There may be issues that have happened prior that -- quality issues, other things -- I'm just giving general statements, right -- that one has to -- and one going forward on something like blood, you want to

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be -- so you want to have the highest standards and work toward there.
And the reality is, you buy a company, and there may be issues. And you have to address those issues.
Q. Okay. Because, I mean, in complying with FDA laws and requirements, that's very important for a medical device company?
MS. STOKES: Objection. Form. Argumentative.
THE WITNESS: Sure.
BY MR. JESSEE:
Q. And so you are being brought in as the chair of the quality committee? And is that essentially --
A. No. I was brought in as a board member.
Q. And then you eventually became the chair of the quality committee?
A. The quality committee is the committee of the board.
Q. And the quality committee though --

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it's basically sort of -- is it similar to a compliance committee or its compliance with FDA regulations?
MS. STOKES: Objection.
THE WITNESS: It has to do with -- but it's more focused on quality.
BY MR. JESSEE:
Q. And are you regularly consulting with either employees or management at Immucor in that position?
MS. STOKES: Objection. Form. Vague.
THE WITNESS: That would be fair.
BY MR. JESSEE:
Q. So, for example, with regard to regulatory submissions, is that something that, from time to time, you would get consulted with?
MS. STOKES: Objection. Form.
THE WITNESS: I may, yes. Certainly.
BY MR. JESSEE:

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Q. And with respect to any of the -- whether it's inspections or things of that nature by the FDA, would that be something you would be consulted with?
A. Absolutely. That may be the case.
Q. And Immucor is -- they have actually submitted a number of 510(k) applications over the years, right?
MS. STOKES: Objection. Form.
THE WITNESS: A number of -- including -- and PMAs.
BY MR. JESSEE:
Q. Were you involved in any of the 510(k) applications?
MS. STOKES: Objection. Form.
THE WITNESS: I have to go back and -- I'd have to refresh my memory, which ones were PMAs and which ones were 510(k)s. I would want to refresh my memory.
BY MR. JESSEE:
Q. Is there -- have you consulted with -- we're talking about nonlitigation still

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here -- with any other companies besides Immucor on any either 510(k)s or premarket PMA applications?
MS. STOKES: Objection. Form. Compound. Vague.
THE WITNESS: Yes.
BY MR. JESSEE:
Q. Which are those?
A. I'm not sure what's public. And I would want to check with those companies to what -- before I -- I would want to have counsel here, but they would probably be TPG related is my guess.
Q. And what -- and without identifying a company, just generally, what would your role have been in those instances?
MS. STOKES: Objection. Answer only if you feel that you can.
THE WITNESS: Generally, they are complex -- complex questions of regulatory -- of what to do.

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BY MR. JESSEE:
Q. In other words, you are not -- they are not having you write the -- a 510(k) submission or PMA or to -- are they?
MS. STOKES: Objection. Form.
THE WITNESS: No. I would not be sitting there, but I would be telling them -- they may be asking me what they should be writing.
BY MR. JESSEE:
Q. Okay. And, basically, to get advice on a specific topic?
MS. STOKES: Objection. Form.
THE WITNESS: Specific topic, strategy, you know. It's vague, a little vague. There were specific questions -- there were questions that I was asked in different parts of the regulatory process.
BY MR. JESSEE:
Q. Okay. How many times has that happened outside of Immucor?
MS. STOKES: Objection. Form.

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THE WITNESS: I mean, there is one that happened pretty recently that's on top of my mind. I don't -- I'd have to go back and think. There was certainly one this year -- I'm sorry -- last year, because we are January, one last year.

My guess is probably, of that kind of nature, maybe one, two a year.

BY MR. JESSEE:

Q. And the one from last year, was that a PMA or 510(k) device?

MS. STOKES: Objection. Form.

You know, if this is confidential, then don't answer.

THE WITNESS: He is not asking me what the name of the company is.

BY MR. JESSEE:

Q. Yeah. No. I am trying to be very careful, Doctor.

A. And I appreciate that. You are not asking me the name of the company.

I don't recall specifically. I'd

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have to go back and double-check. I just don't -- I don't have the file in front of me.

Q. Oh, sure.

A. I didn't think that's -- I don't -- that's not what I focused on to prepare here.

Q. Understandable. And, again, you know, I am just trying to -- I want the best of your recollection.

A. Sure.

Q. It's definitely not a memory test here.

A. Sure.

Q. You are not critical of a company that decides to use the 510(k) regulatory pathway to bring a device to market, are you?

MS. STOKES: Objection. Form. Vague. Argumentative.

THE WITNESS: The answer probably to your question is, it depends.

BY MR. JESSEE:

Q. What does it depend on?

MS. STOKES: Same objections.

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THE WITNESS: Give me -- give me some more facts. So if you -- if you have a question that raises new questions of safety and effectiveness, right.

Let me give you -- let's be direct. If you -- take here, 1997, Bard Composite Prothesis, 1997.

At that stage, I wouldn't want to say always, but, in general, for example, polypropylene was not used intraabdominally. I mean, there may have been some surgeons here or there who used it, but it was not used intraabdominally.

A company comes and says, Okay. We're going to use the 510(k) process. We had Marlex, and that's polypropylene. And we are going to -- there's Gore-Tex, and that's ePTFE.

And we're going to put it -- make a device now that has -- where we're going to take that polypropylene, and we're going to market it for intraperitoneal use. And we believe that the ePTFE is going to protect it.

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And when you look at the 510(k), the question is, Are there new safety characteristics to that device? And they say, Well, it's just Marlex, and it's just Gore-Tex. We'll just put those things together.

I mean, that raises new safety and effectiveness -- new safety and effectiveness characteristics. And it's going where no one else went before, and it didn't get human trials and yet went through 510(k).

So I would be critical of that, because it would put patients at risk without the kind of studies that should be done when you do something new and you push the field.

So if you rely on something being the same, which is substantial equivalence, but if you take that device, for example, and you look at the marketing for that device and it says, Bard, you know, this device is the first prothesis to directly address that concern with something new, how could it be substantially equivalent?

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So I would be critical. Substantial equivalence should be used for something that is the same. It doesn't raise new questions. It's as safe as something on the market. It doesn't raise new questions.

If you are saying it's substantially equivalent and then go out to market it as new, I would be critical.

BY MR. JESSEE:

Q. Okay. There is a lot in that answer there. So let's see if we can unpack it.

First, you mentioned that Marlex hadn't been used intraabdominally. I think the example you were giving was the composite mesh when it was cleared in 1997 right after -- a couple months after you left your position?

A. In August. Correct.

MS. STOKES: I'm going to object. It misstates.

Go ahead.

THE WITNESS: The date was in August. I was not there.

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BY MR. JESSEE:

Q. Yeah. A certain amount of months -- you left early in February, I think you said, 2000- --

A. End of February.

Q. 1997.

A. I'll tell you the day that I left off the camera.

Q. What is your understanding of when Marlex mesh was used intraabdominally?

MS. STOKES: Objection. Form.

THE WITNESS: My sense was, there was a general view -- I would have to go back and tell you -- that it was not to come into contact with the bowel.

From the very beginning, there was as this says there was concern that, you know, the may shift, and you did not want it to come in contact with the bowel.

And that was the general understanding back in the 1990's. So you didn't use it. And that was -- you couldn't use it. You shouldn't use it.

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Now, whether some surgeons used it here or there, but the general position was that you didn't use it for intraperitoneal use, because it was known that it could cause adhesions.

Exactly when in the history that was known, I'm not sure, but, certainly, throughout the 1990's, the reason for this Composix device was, we need -- here -- Bard is basically saying, We're going to give you something unique that is new that is going to protect that mesh. You don't have to worry about that polypropylene coming in contact with the body.

That was what the promotion said.

BY MR. JESSEE:

Q. Okay. Just so we're clear, when you're saying new, ePTFE obviously is not new, because there are a dozen ePTFE devices at least that were cleared while you were commissioner, right?

MS. STOKES: Objection. Form.

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Misstates. Argumentative.

Go ahead.

THE WITNESS: So ePTFE was not a composite. The issue was not ePTFE coming in contact with the bowel. The issue was polypropylene coming in contact with the bowel.

And for this device, it says Bard -- the composite is the first prothesis to directly address this concern, right?

And the composite mesh contains two different clinically proven materials to maximize tissue in growth in surrounding wall mitigating the risk of visceral adhesion.

BY MR. JESSEE:

Q. And can I ask what you are looking at?

A. It's part of the 510(k). It's part of the --

Q. And would you mind -- is there a Bates number on that?

A. Yes, it is. MPPE 13970570. But it's in the 510(k) application, I believe.

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So this is clearly something new, and it's -- I mean, you know, it says the first composite mesh prothesis, and it's uniquely designed.

So why is that going through a 510(k)?

Q. And so this was in -- what you are reading from is in the 510(k) submission.

Are you critical of the FDA reviewers of that 510(k) submission?

MS. STOKES: Objection. Form.

THE WITNESS: I am not here to testify, I mean, I don't think, about FDA. I mean, I think that if you look at the application, the 510(k) application, Bard did not raise this issue of polypropylene coming in contact with the bowel.

In the algorithm, it talked about ePTFE being new, right, but this risk of now the polypropylene and that raising the safety questions, that was not addressed by Bard in its application.

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So is this one where the company didn't bring this to FDA's attention? Should FDA have caught this? Would I have liked FDA to catch this?

If you go read that 510(k), it doesn't say that, Hey, these are new -- these are new questions, and this is the first time we are doing this. And this may lead to problems.

That's not what -- when you read the application, that's not what it says.

BY MR. JESSEE:

Q. In looking at your testimony a little while ago, you said that it was commonly known during the 1990's about the polypropylene.

If you place it intraabdominally, then you have that risk of adhesion.

MS. STOKES: Objection. Form.

THE WITNESS: So I think that was fair in the industry, and I think that was fair among hernia -- other surgeons can testify.

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I can't tell you what FDA knew -- what FDA knew exactly about that issue. That issue was not, I mean, raised in any -- with any prominence when I go read the application for this.

So, I mean, I think if you want to be critical -- if you want to be critical, you have to -- it's the obligation of the manufacturer to raise these issues and say, Hey, this is unique. This is new. This is the first prothesis.

This raises, right, new safety characteristics that have not been answered before. I mean, that's the real question.

I mean, has anyone really studied this new device and -- in humans and answered these questions? And the answer was no. And that clearly should have been done before this device got on the market, because it was unique. It was new. You were adding new risks.

There were some animal studies done.

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We could discuss those, but there were certainly no human trials done. And that clearly should have been.

BY MR. JESSEE:

Q. And so going back to my question -- if you can't answer it yes or no, that's fine, but are you critical of the FDA reviewer for that composite 510(k)?

MS. STOKES: Objection. Form.

THE WITNESS: I think I answered that. I think based on the application of what the company -- based on the fact that the company didn't highlight this and didn't raise these questions with FDA, it's hard to be critical, because the responsibility rests with the company.

Would I have liked FDA to catch it and said, Hold it. This is unique. This is new. This raises new characteristics that have not been studied in humans before? Yes, I would have liked FDA to catch that.

So is that being critical? I mean,

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again, I'm not -- that wasn't one of the questions that I was assigned to ask, but I would have certainly liked FDA to catch it, but it's because your client didn't lay this out to the FDA. The FDA is only going to be as good as what your company lays out.

BY MR. JESSEE:

Q. And you understand that several of the surgical mesh products on the sheet we looked at that were cleared by your commissioner were -- contained two different mesh materials.

MS. STOKES: Objection. Form. Assumes facts.

THE WITNESS: Show me which materials they contained.

BY MR. JESSEE:

Q. Well, for example, let's just look -- we can just look at the titles of them. For example, we see -- I am looking at -- on the second page of the document we have in there.

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A. Yes, sir.

MS. STOKES: Just so the record is clear, I just have a running objection on this -- usage of this document period.

BY MR. JESSEE:

Q. So, Doctor, do you see the -- where it states -- I'm looking at the September 3rd, 1996, Gore-Tex dual mesh plus biomaterial with holes?

A. Yeah. So as I understand it -- again, give me the 510(k), and we can -- why don't you pull the 510(k) for it and I am happy to discuss it.

As I understand this, okay, your device, the Composix, was the first polypropylene plus any PTFE layer.

As I understand, Gore-Tex -- and, again, you would have to give me the 510(k), but the Gore-Tex were different layers of ePTFE.

Your company says this is the first polypropylene ePTFE in this document. Then I

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have no --

Q. In the application to the FDA?

A. In this promotional piece.

Q. But you are reading from the 510(k), I thought you said earlier.

A. This is a piece in one of the -- one of the fact materials. And FDA raises questions about this and says, You can't make these claims about minimization of adhesion risk.

Q. Okay. So FDA --

A. The FDA caught that.

Q. All right. So they were aware of that -- they were aware of that issue then when they were reviewing the 510(k), correct?

MS. STOKES: Objection. Form. Argumentative.

THE WITNESS: You are now asking me to do something that you asked me prior that I said I would not do, but you are asking me for FDA's subjective state of mind and what they knew and what they were aware of.

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I can show you objectively that this was -- this was one of the pieces of paper in that application, and FDA objected to this, but what it focused on here was that you can't say minimize the risk of adhesion -- adherence to the bowel. That would be improper.

BY MR. JESSEE:

Q. And I understand you are not offering opinions on the FDA's state of mind or knowledge.

A. Thank you.

MS. STOKES: Is there a question?

BY MR. JESSEE:

Q. And you are not offering opinions about Bard's state of mind or knowledge, are you?

A. Correct.

MR. JESSEE: And, Doctor, we have been going for an hour and a half. I am happy to keep pushing on, or if you want to take a break, we can do that as well.

Anyone?

THE REPORTER: A break is good.
MR. JESSEE: All right. Let's take just a couple minutes.
THE VIDEOGRAPHER: We are going off the record. This is the end of Media Unit No. 1.
The time is 9:32.
(A short recess was taken.)
(Deposition Exhibit 8 was marked for identification.)
(Deposition Exhibit 9 was marked for identification.)
(Deposition Exhibit 10 was marked for identification.)
(Deposition Exhibit 11 was marked for identification.)
(Deposition Exhibit 12 was marked for identification.)
(Deposition Exhibit 13 was marked for identification.)
(Deposition Exhibit 14 was marked for identification.)

(Deposition Exhibit 15 was marked for identification.)
(Deposition Exhibit 16 was marked for identification.)
(Deposition Exhibit 17 was marked for identification.)
THE VIDEOGRAPHER: We are going back on the record. This is the start of Media Unit No. 2.
The time is 9:49.
BY MR. JESSEE:
Q. Dr. Kessler, during the break, we've had some discussions, and we've been discussing with your counsel how we're going to deal with the numerous different large paper documents you brought.
And we're going to continue to figure that out at the next break, but I want to just -- I've marked them as exhibits.
So I just want to briefly -- if you could confirm for me that we're -- I have them correct and what we're talking about.

And what I marked as Exhibit 8 is the --
A. May I stand?
Q. Please, please. And, like I said, don't feel -- no need to ask me. You are welcome to stand whenever you'd like.
A. May I get untangled?
Q. Yeah. Let me see if I can help you here.
And I have marked as Exhibit 8 a document that has a tag on the front that says "3DMax"?
A. Correct.
Q. And is it -- so did you create this entire document?
A. Yes.
Q. And that includes the cover page that lists numbers on it?
A. No. I dictated this. This was done -- somebody typed it, but I dictated -- I said -- I said exactly what these words are.
Q. And who actually typed it up?

A. Gerard, at my request, but I said, No. 1, this. I just -- I had someone type it.
Q. And so that's someone from plaintiffs' counsel --
A. Yes, I actually did the typing, but this is my -- I dictated this.
Q. What about the cutting and pasting? All you?
A. Yes. I mean, I'm not saying they didn't use some scotch tape here or there to --
Q. Make sure it stays there?
A. Yeah. Exactly. That kind of stuff. They did help me on that.
Q. Did you determine what you cut out within there?
A. Oh, yeah.
Q. And is all that -- there's handwriting, and this is on a number of -- is that all your handwriting?
A. We'd have to go through every page. I don't want to swear, but this is certainly my handwriting.

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Q. So we have Exhibit 8, the 3DMax.
Exhibit 9 is the Quintiles?
A. Correct.
Yes. Exhibit 9 is Quintiles. Yes, sir.
Q. Exhibit 10 is going to be large Ventralex buckling?
A. Yes.
Q. Exhibit 11 is PerFix Plug?
A. Yes.
Q. Exhibit 12 is Ventralight ST?
A. Yes, sir.
Q. Exhibit 13 is MSDS?
A. Yes, sir.
Q. Exhibit 14 is infection?
A. Ventralex infection.
Q. Excuse me. Yeah. Thank you.
Ventralex infection?
A. Yes.
Q. Exhibit 15 is Ventralex ST?
A. Yes, sir.
Q. And then Exhibit 16 is the one

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that's titled "All devices"?
A. Yeah. They're really -- they're just studies, just so we understand.
Q. And then Exhibit 17 is just these nine binders that you brought with you?
A. It's the first of nine.
Q. Right.
And is those -- are those binders -- I can tell from the cover of them. Those look like something the attorneys sent to you?
MS. STOKES: Objection.
THE WITNESS: Well -- so these were done -- all these are, are for each paragraph, what I asked to be made. For every paragraph, there is -- anything that is cited in that paragraph is behind that tab, and anything that is quoted in my report may be highlighted.
So -- but it's -- basically, it matches my report. It's just anything that is cited in the report. And if there is a specific quote, that quote may be highlighted.
BY MR. JESSEE:

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Q. So were those binders created after your report was finished?
A. Yes.
Q. As far as --
A. And you should have all those documents, because -- I mean, if you want copies, you -- but you already have everything there.
Q. Right. And in those -- and just -- I just took a very quick look.
And feel free to sit down, Doctor.
You didn't think you would probably be getting this much exercise during your deposition.
A. That's fine. Here is some exhibit tabs.
Q. I notice that there is some highlighting and flags in those binders?
A. Yes. So that matches -- I said if there's a quote that is quoted, that is the page -- that flag identifies where that quote is.
Q. Right. And the flag -- my question

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is, the flags and the highlighting, is that all your doing, or is that counsel's?
A. So I identified the quote, but they identified where that -- I mean, again, when they put the binders together, they highlighted the quote that was in here.
Q. Okay.
A. Again, I don't want to get -- I want to be careful on work product rules and what's -- I mean, there is no secret here.
Q. Yeah. I just want to know -- all I want to know is the timing --
A. That just is -- if you ask me Paragraph 22, this quote -- this document says this, I can pull that up and turn to the flag, and that's the actual document.
Q. And did you use those binders in preparing for your deposition today?
A. I think that would be fair.
Q. Did you review them?
A. I didn't turn to every page.
Q. So more as a resource as you were

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going through your report? If you had a question, you could go look at them?
A. That's exactly correct.
Q. And as far as the large -- I don't know if you have a better description than I have -- the large --
A. Sheets?
Q. Yeah. The collage with the different pictures that you made, did you determine what subject each of those would be?
A. Absolutely. That is only me.
Q. Okay.
A. Somebody may have -- again, may have helped me tape or clip or helped me do the index, but I dictated that. That's all me.
Q. Is that something you did after your report was written or before?
A. I don't remember exactly. I mean, I may have had sheets before. I may have had sheets after this.
Q. Was the purpose to -- of making those sheets just to help collect your thoughts

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on a particular issue and have a reference or --
A. That's a fair statement.
Q. Did you use those in preparing for your deposition today?
A. I'm sure you're going to ask me -- to prepare for my deposition? They were done. I mean, what I mean, prepare, I mean, they were part of the process of collective -- everything in my brain.
I mean, they do affect what is in my brain in some ways, because when you cut and paste and you focus on certain things and you put it down and you look at it, that certainly helps me prepare, right? So I guess the answer would be yes.
Q. On the large sheets that you have there -- and we just walked through the different topics -- one topic that I don't see covered in your expert report is the MSDS or material safety data sheet?
A. Correct. As you know, your expert,

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Donna B. Tillman raised that issue. She was the FDA -- I assume fair to refer to her as the FDA expert from your side.
So she raises that issue, and that's the reason I went to look at the MSDS question, because your FDA expert raised that question.
Q. Do you know if we have any other experts that worked at the FDA besides Dr. Tillman?
A. That was the --
MS. STOKES: Objection. Form.
THE WITNESS: I don't know the answer to that question. That was the one that was identified for -- that was the one that was -- that I knew.
BY MR. JESSEE:
Q. Okay. Is that the only defense expert that you know in this case?
MS. STOKES: Objection. Form.
THE WITNESS: I have to go back and look. You can look at my reliance list. That was the one that I focused on.

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BY MR. JESSEE:
Q. Sure. Why don't we take a quick look at your supplemental revised list that was provided to us and we've marked as Exhibit No. 3?
A. Correct.
Q. And this was a -- is, again, as I mentioned earlier, a reliance list that was provided to us yesterday.
And it lists at the end of it a handful of depositions and two expert reports?
A. Correct.
Q. And the two expert reports listed are expert report of Don B., which -- yeah. It's a typo.
A. It's Donna B.
Q. Yeah. It's Donna B. --
A. Yeah. I'm sorry.
Q. -- Tillman.
And I think the date is wrong, but you received --
A. That was my -- in fact, that's the

date of my report, right?
Q. Exactly.
A. So I apologize. I actually have it here somewhere.
Q. Did you -- did you type up this --
A. No, I did not.
Q. Did you dictate it?
A. Yes. Or I gave -- or I gave materials. I mean, I may have had materials and said, Here is materials, etc.
Q. And also listed here is the expert report of John L. Quick?
A. Correct.
Q. And --
A. But I had Quick's report. It should be on my original list. It was -- I had certainly -- I cited Quick's report in my report, and I had it, I believe. So it should be on my original reliance list.
Q. Did you request the report for defendant's FDA experts?
A. I don't recall whether I said it

that way. I don't remember what I exactly said.
Q. Well, did you request any expert reports?
MS. STOKES: Objection. Form.
THE WITNESS: I certainly requested Quick, right, on defense side. I may have asked what came in after my -- I may have phrased -- the question may have been to counsel, Tell me what came in that is relevant to me or to FDA.
Don't hold me to the exact question.
And, again, I want to be careful under the federal rules. I'm getting very close --
MS. STOKES: Yeah, yeah. It's --
THE WITNESS: I'm getting very close to what I'm -- I'm having conversations with counsel.
But this was -- on my initiation, I asked the question, and I got Dr. Tillman's report.

BY MR. JESSEE:
Q. Okay. As far as the other -- while we have this out, the other documents that are listed on your supplemental reliance list, can you -- the produced documents, the first section in this document of Exhibit 3, is just -- there's a number of Bates numbers listed.
Do you know what the -- any of these documents are?
A. I'm not -- I'd have to look. I'm sure I -- I'm sure I would know if I looked. I mean because I looked. But I just don't know the -- the Bates numbers. Sorry.
I -- I -- I don't -- I have access, and I requested access to the discovery database. And I have continued to search that database. And to the extent that -- you know, you always get back hits. I try to be -- to make sure you have a sense of what I've seen or seen -- think that's relevant or even considered since my report.
Q. Okay. Is -- are these all

documents, the documents listed in the "Produced Documents" section of the supplemental reliance list, documents that you found?
MS. STOKES: You're getting dangerously close to work product here.
MR. JESSEE: I'm happy to discuss.
MS. STOKES: So --
MR. JESSEE: I don't think -- I think it's pretty clear in the rule though about what he relied on and what he -- his opinions are based on and the assumptions he was given, too, are all not work product.
But I -- I -- I hear what you're saying. I'll be careful. I'll --
MS. STOKES: So try to --
MR. JESSEE: And you're welcome to --
MS. STOKES: Please, Counsel.
MR. JESSEE: Any -- I mean you're welcome, if you think I cross a line, to instruct him not to answer. But I don't think

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I've gone there yet.

THE WITNESS: So -- so they are -- the majority of documents -- I mean I do a great deal of searching myself.

MR. JESSEE: Uh-huh.

THE WITNESS: I wouldn't -- would not want to represent that I find every document. I think that would be a mistake. But I -- I think I find the vast major -- I mean the vast number of these documents I've looked at are things that it find on the -- but sometimes I -- my search capabilities are limited sometimes. And we can get into the quality of the database and the quality of the discovery.

So there are many time -- there were many times where -- even last night where I said -- I find a document, but I can't find -- it's -- it's only a partial document, and where is the rest of the document.

So usually these things get stimulated by me in some kind of format.

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BY MR. JESSEE:

Q. Do you -- can you tell me, in looking at the supplemental reliance list, which ones that you independently found and which ones were provided to you?

MS. STOKES: You know what? I'm going to object and just -- this is -- we're -- we're too close to work product. So I'm going to instruct him --

MR. JESSEE: Okay. Are you instructing him not to answer?

MS. STOKES: Yeah.

MR. JESSEE: All right. And then we can take this up with the Court. That's fine.

BY MR. JESSEE:

Q. The -- Doctor, what the -- the next section's published literature, right?

A. Again, just so you know, the -- the -- the vast majority of documents I find myself --

Q. Okay.

A. -- you know, on -- on discovery.

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But I -- but I do sometimes ask for people to do searches and see if you can find me -- "Can you find me these animal studies on this device?" Because I -- I see some reference to them, but I don't see -- I can't find the exact -- or I mean this exact study.

I would see a reference, for example, on a 510(k) to an animal study. And I said, "Can you try to search for the original study report?" So that's the kind of back and forth that -- that happens.

Q. Okay. With the produced documents listed here, are these all documents then that you would have reviewed after you wrote your expert report?

A. You know, again, these tend to be -- one of the problems when you get a lot of documents is -- for example, the Quick document. I know you pointed to this. But Quick I certainly did review, you know, the day of and that section of Quick that I cite in the reports.

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So there's a lot of paper. I don't want to say everything is since my report.

Q. Well --

A. There may be some overlap here.

Q. And -- and I guess my -- I'm focusing right now just on the "Produced Documents" section. And I'm just trying to figure out if these are documents that you -- were just not -- accidently not included on your original reliance list or if these are documents that you have reviewed since then and are -- have opinions on.

MS. STOKES: Objection. Form.

BY MR. JESSEE:

Q. Do you understand what my question is?

A. Yeah. I mean there's a number of parts to your questions.

I'm not sure you should take home that I have opinions on these, on all these documents. I -- I don't want you to think that.

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I'm just trying to -- you want to -- I think your depo notice asked for -- I mean we can go pull -- basically you're asking for everything that I have.

So I'm trying to -- here's what I have. I don't want you to think -- there's nothing here that -- well, the only thing here that -- I don't want to say new opinions. I'll leave that to -- how you raise --

Q. How -- and maybe -- if I could make a suggestion, maybe we could say opinions not in your report that you --

A. Yeah. So -- so -- so -- well --

MS. STOKES: Yeah. I'm going to object to that.

THE WITNESS: I mean I'll -- I'll let the other lawyers characterize what's -- because there's opinions, there's subopinions. There's -- this is, you know, what you're asking me about.

I mean there's this issue of the MSDS, right? Tillman raised this MSDS, for

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example, in her report. I view -- she's the -- I view her as the, you know, defense's -- FDA expert, right? So obviously it was of special interest to me.

So I went to study what Tillman raised, right? I disagree with Tillman, for example.

BY MR. JESSEE:

Q. On the MSDS issue?

A. On the MSDS issue, right? I mean -- and when I went to study it, I mean I certainly see that, you know, there was a potential safety hazard in the degradation issues in the Phillips technical file that was linked to the MSDS sheet and that that would -- and that Tillman says FDA only requires studies on the finished product. That's not accurate.

Because ISO 10993, Part 18, requires chemical characterization of each component. And that chemical characterization showed -- that chemical characterization showed -- had evidence of oxidative degradation and that

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statement "do not use." So that would certainly be a potential safety hazard that should have been warned about.

I disagree with Tillman. Those documents are here. I saw this issue because Tillman raised it. And you should know that I -- you know, that that's -- those are my comments and views on that.

And happy -- so I brought those -- I wanted you to have those documents. I brought those documents. And happy to discuss that with you.

Q. And, Doctor, we can agree that material safety data sheet's not referenced in your expert report. All right?

MS. STOKES: Objection. Form.

THE WITNESS: I'd have to go through the entire reliance list. It's -- it's not discussed -- I mean I -- I didn't see the issue -- I didn't see the issue -- I don't see the issue discussed in my report.

It came to me -- I didn't discuss

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the issue in my report. It may be -- have some references that go through the reliance list. So I don't want to -- I'd have to check that.

But I -- I became aware of that issue when Defense raised it in that. And I understand there's -- you know, I don't know what the -- I'll leave it to lawyers.

I mean I just want to let you know I disagree and view -- I think she's wrong. And I think there's an obligation and responsibility to put potential safety hazards. And there was a potential safety hazard in -- in that technical file about degradation and do not use. And that was not warned about.

MR. JESSEE: Right. And --

THE WITNESS: You -- you should know that --

MR. JESSEE: No. And I appreciate you --

THE WITNESS: -- that's the responses to Tillman. And the Court and you can discuss is that rebuttal, is that --

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MR. JESSEE: Sure.
THE WITNESS: And you're -- I want you to be able to inquire -- I want you to be able to ask me all questions about that. But that's how I came to the issue.
BY MR. JESSEE:
Q. Yeah. And I appreciate your candor there.
And what I -- my question, though, very narrowly, is you don't offer any opinions about the MSDS in your actual expert report that was served in this case; is that...
MS. STOKES: Objection. Form.
THE WITNESS: No. But I think -- but -- that would be correct. But I think in response to Tillman I certainly have that as an opinion.
BY MR. JESSEE:
Q. Have you supplemented your expert report?
A. Just with this -- just with this -- just with the reliance list --

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Q. Okay.
A. -- and the MSDS documents.
Q. And you actually did an errata sheet as well to your expert report, correct?
A. Yeah. I'm -- I'm happy to put it on the errata sheet if you'd like. I mean I just want to -- if want me to put -- list this as -- I mean I'm not sure what the right -- tell me what the right way is. Counsel can decide.
If you want me to supplement now and -- I just want to make sure you know I have this view in response to Tillman. And this is an -- obviously it's an important issue to counsel. It was raised by Dr. Tillman. And it should have been warned about.
Q. Okay. And it's not an issue though that you were asked to look into by plaintiffs' counsel, right?
MS. STOKES: Objection. Form.
I'm going to instruct him not to answer.
MR. JESSEE: Well, this is from his report.
BY MR. JESSEE:
Q. You list out the issues you were asked to look into, right?
A. Yeah. But you -- you didn't ask the -- you -- you didn't ask the question "At what point in time did counsel instruct you?"
So I mean, at that moment --
Q. And --
A. -- in time, no. I mean -- so I was -- I don't want to get yelled at by my counsel.
THE WITNESS: And -- but -- just let me see if I can be helpful. Okay?
MS. STOKES: Go ahead.
THE WITNESS: Okay. So again, I was asked certain questions. I responded to those questions. I read the report that was served -- that -- that criticized me. I mean --
BY MR. JESSEE:
Q. Well, no. I don't think that's fair. That -- that -- it does not -- does the

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report criticize you, or does it disagree with your opinions?
MS. STOKES: Objection. Form.
Is there a question here?
THE WITNESS: I'm sorry. I don't mean to be -- it shouldn't be on me. It -- it disagrees with my opinions. But it's the -- it's the -- I -- it's the report --
BY MR. JESSEE:
Q. I -- okay.
A. It's the --
Q. I just want to make sure we're on --
A. -- matching report.
Q. I want to make sure we're on the same page. And -- because --
A. Yeah.
Q. You don't criticize Donna B. Tillman as a person or her qualifications; you disagree with her opinions, right?
MS. STOKES: Objection. Form. Argumentative.
THE WITNESS: Yeah. That's correct.

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I mean I'm -- I'm -- I'm not -- of course. I would not -- that's not what this is about. This is this is about the substance of --
Q. Okay.
A. I mean --
Q. I just wanted to make sure we were clear.
A. Yeah. No. I don't -- but -- but she raised me in her report, right?
Q. Your opinion -- your report and opinions, right?
A. She -- she -- my opinions were raised in her report --
Q. Okay.
A. -- that I read.
Q. Sure.
A. She raises the MSDS. I was not asked -- counsel certainly is aware that, because of Donna B. Tillman's report, I -- I looked at the MSDS. So I mean -- and -- and, again, I don't want to relay private conversations.

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But it would be fair to assume because -- that -- I -- I don't -- I don't want -- she can --
MS. STOKES: Yeah. I --
THE WITNESS: -- represent what she knows.
But what -- what she asked me since then -- she can discuss whether I'm allowed to talk about that.
But I do have issues with Dr. Tillman's on MSDS. I have views of the MSDS. I brought these MSDS sheets. I put these here. Feel free to inquire about this.
I'm happy to answer everything about -- I think I've told you my views of MSDS and gave you --
MR. JESSEE: Yeah.
THE WITNESS: -- a snapshot. And happy to discuss them more.
BY MR. JESSEE:
Q. And, Doctor, today I want to focus on your expert report. Because that's the

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purpose of this deposition. And we might -- we'll see if we get into that topics at all.
But --
A. Right.
Q. -- just so I know, are there any other issues or opinions you have that are not in your expert report that you've developed since you put the expert report together?
MS. STOKES: Objection. Form.
THE WITNESS: So let me just say --
MS. STOKES: Mischaracterizes.
THE WITNESS: -- I'm happy to sit here during lunch or whatever and ask any -- answer any questions you have on MSDS. I mean I'll -- if -- if you want to --
BY MR. JESSEE:
Q. Well, and I know you're --
A. I --
Q. But to be fair, Dr. Kessler, you know, I didn't know about this opinion until I came in here today. And so you know, I didn't get a chance to bring in documents that I would

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want to ask you about when -- you understand what I -- where I'm coming from?
A. I -- I -- I --
MS. STOKES: Is there a question?
THE WITNESS: I -- I --
MS. STOKES: Objection.
THE REPORTER: I need everyone to talk one at a time, please.
MR. JESSEE: And -- but I appreciate your offer. Why don't we just say we'll move on, and we can figure it out with the Court if we need be on a --
THE WITNESS: Sure. But -- but, again, you certainly knew that your expert raised this. I mean -- and your expert raised it in the context of -- also of my -- my testimony was in -- my opinions were in her report, and she raised this issue.
So I don't think it's a new -- I mean, again, I leave it to you and the lawyers to work out.
BY MR. JESSEE:

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Q. Do you know if plaintiffs' others expert address MSDS in their reports served on December 4th?

MS. STOKES: Objection. Form.

THE WITNESS: I -- I'd have --

MS. STOKES: Assumes facts.

THE WITNESS: I'd have to go back and look and see whether Quick raised it. I think it was raised in Quick, if my memory serves me right. But I don't want to -- I don't want to testify.

BY MR. JESSEE:

Q. Okay. And we'll talk about Dr. Quick.

And you relied on his opinions, in part, in your -- in forming your opinions, correct?

MS. STOKES: Objection. Form.

THE WITNESS: I think I -- I certainly cite -- I think it's cite -- I cite his opinion. And I think, as long as you include, in part, I mean I'm happy to testify

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independently of Dr. Quick. I don't think I'm dependent on Dr. Quick.

But I wanted -- you know, there is -- he has certain expertise, and I do cite that.

BY MR. JESSEE:

Q. Well, and the point I was getting at though is that you -- you saw his expert report and cite to it in your expert report.

So you saw it at some point before you put together your expert report finalized right?

A. I mean correct. I -- I -- but -- so we can be -- well, again, I don't want to violate Rule 26 here. So I want to be careful of what -- yeah.

So I -- yes, I did see it. But there's one section of Dr. Quick that I had certain questions about. So there's one -- it shouldn't be all of Dr. Quick.

Q. Were you provided with all of Dr. Quick's report or just that one -- just one

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specific section?

A. So the answer is both, I think would be accurate.

Q. Okay. And we're talking about the -- and just so we're clear, I'm talking about the time period before your expert report was finalized in December 4th, you had the whole report.

A. Can I explain?

Q. Yes, sir.

A. So a few days -- I had a specific question, I believe, that focused relatively narrowly on a certain issue. And I saw -- I believe I saw that section of the report several days before.

And then I saw the final report the last day, I believe in the morning, whenever, sometime. So I didn't see the whole report until the end. But I saw the -- the -- that relevant portion I had asked for before because I had to prepare my report.

Q. Okay. And was that e-mailed to you,

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the -- that portion that was before or --

A. I -- I -- it probably was Webex or something. I saw somehow. I don't recall.

Q. So going back to the question I asked a little while ago. I just want to make sure I'm being clear here.

We've talked some about the MSDS, this opinion that's not in your report.

Are there any other opinions that you've developed since your report, besides the MSDS, that are not in your report?

MS. STOKES: Objection. Form.

THE WITNESS: Well, it depends. I mean -- so let -- can you re -- rephrase -- can you ask -- the report -- I mean we talk -- we -- we've been on the record for two hours or so. I mean I've given you certain testimony.

Is that testimony included in your question?

BY MR. JESSEE:

Q. Well, Doctor, you've done a number of expert reports over your career, right?

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A. Right.
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. And I -- you understand that it's important, in doing an expert report, to be thorough and make sure your -- all your opinions are contained in there, right?
MS. STOKES: Objection. Form.
THE WITNESS: Correct. But I also understand that I'm here. You're asking me questions. And during that testimony, I may give you certain opinions. There may be -- there may be subopinions or subsubopinions or maybe an observation that relates or a set of facts that relates.
So I -- so my goal was to put everything as best I can, right, schedules and every -- and four corners.
Had that report -- had you stopped taking that report and said, "We're done," we -- we've been engaged in test -- in -- in questions, I would say that reported reflects

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the four corners.
Your -- what I would say right now is that my opinions reflect that report and anything we've discussed on the record.
BY MR. JESSEE:
Q. Okay. Well --
A. And -- and if we stop now, I would say that -- that the four corners are that report and -- and the record you've asked me about. And I won't have any more -- I won't have anything else to say if you stop right now.
But if you ask other questions, I may have other opinions or subopinions or characterize them as you want. You know, I'm answering your questions.
Q. Are you trying to incentivize me to stop now? Is that what I'm -- what we're getting at?
MS. STOKES: Objection.
THE WITNESS: I -- I -- I don't --
MR. JESSEE: I'm just kidding.

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THE WITNESS: I don't think you would take that bait, sir. I mean, if you'd like, you know --
BY MR. JESSEE:
Q. Let -- let me ask you a different question that's a little better, I think, maybe so we are on the same page.
The -- are there -- have you developed opinions on any topics that are not covered in your expert report since that time other than the MSDS?
MS. STOKES: Objection. Form.
THE WITNESS: I think we talked about -- I mean we talked about composites this morning, right?
BY MR. JESSEE:
Q. Is that though -- is that an opinion that you have had previously?
A. You asked me --
MS. STOKES: Objection. Form.
THE WITNESS: You asked me whether I had criticisms of FDA, right? And we -- you

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asked me whether I had -- you asked me whether I would criticize a company for using substantial equivalent.
I think that was your question, right?
MR. JESSEE: Something like that.
THE WITNESS: And I answered that question.
Now, is that an opinion? You know, the Court can character -- I mean I answered your question. That is something I -- did I phrase it exactly that way in the report? Probably not. Because there's limitations. But, you know, you could view that -- you view that for what you want.
BY MR. JESSEE:
Q. Okay. And, Doctor -- and, to your credit, you did an incredibly thorough report, correct?
MS. STOKES: Objection. Form.
THE WITNESS: There -- there's a -- I -- I appreciate the compliment.

I mean I think the report's pretty focused. Because there are five -- at least five devices. And I try to be pretty focused on there.

But, you know, there's no way I could have -- you know, if I were completely thorough, you wouldn't -- you wouldn't have any questions of me. So I couldn't be that thorough. Because I couldn't have answered all your questions in the report.

But it just -- it's the nature of these things. I mean there's things in the -- the schedules, right? I mean the -- the 510(k) predicate charts. I mean there are issues there, for example, we talked about this morning, what things are relied upon.

So I mean is everything brought out to the exact same degree of attention? No. You -- you understand. But I'm just trying to answer your question.

BY MR. JESSEE:

Q. All right. Let's take a look at

your report --

A. Sure.

Q. -- that was served in this case.

And I'm looking at Page 2, Scope of Report.

A. Correct.

Q. And you list here five issues that you were asked to address in your report?

A. Correct.

Q. And those issues were -- the first one is the purpose of the 510(k) process, the import of FDA clearance through the 510(k) process, and FDA standards and regulations for the inclusions -- the inclusion -- excuse me -- of warnings on device labeling?

A. Yes.

Q. That's the first issue you were asked to address?

A. Yeah.

Q. Second issue was whether Bard admitted certain warnings from the labeling of the PerFix Plug, Ventralex and 3DMax device?

A. Correct.

Q. The third issue is whether Bard's marketing of the PerFix Plug and Ventralight devices was misleading?

A. Correct.

Q. The fourth issue was whether Bard's statement regarding reabsorption of the hydrogel barrier in the Ventralight IFU was misleading?

A. Yes.

Q. And the fifth issue you were asked to address was whether Bard failed to follow FDA design control requirements for the large Ventralex and PET ring and Ventralex with PDO ring.

A. Correct.

MS. STOKES: You said "and PET." It's with PET. I'm just...

MR. JESSEE: Oh, thank you. Yep.

BY MR. JESSEE:

Q. The -- this Ventralex with PET ring and Ventralex with PDO ring.

A. Sure.

Q. Then at the end of your report, you contain -- there's a section that's titled "Conclusion"?

A. Yes, sir.

Q. And specifically that starts on Page 90?

A. Yes, sir.

Q. And in that conclusion, that's a summary of the opinions that are expressed in your report; is that fair?

A. Yeah. They just pull down. It's a -- don't view that as in -- I mean inclusive of everything. You got to read -- read the whole report and testimony. I just try to make it easier. I try to give you some kind of road signs, beginning, middle, end.

Q. Right. And --

A. Right.

Q. And that's -- it's a -- of the opinions, and obviously it doesn't encompass all of them.

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But this is the summary of the big points that you hit in your report, right?
A. These are just --
MS. STOKES: Objection. Form.
THE WITNESS: These -- these are the -- I'm not sure big point. These are just things that are pulled down I mean to the end to try to give you somewhat a sense of what's in the report.
BY MR. JESSEE:
Q. Okay. And these address the five topics we -- that you were asked to look at, right?
MS. STOKES: Objection.
BY MR. JESSEE:
Q. That's what's in this Conclusion section?
MS. STOKES: Objection. Form.
THE WITNESS: What I was asked to look at when the report started, yes.
BY MR. JESSEE:
Q. All right. And when -- looking back

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at what you were asked to look at -- and this, again, on Page 2 and 3.
A. Sure.
Q. And we'll look at specifically on Page 3. It's Paragraph 9B.
A. Correct.
Q. Were you asked to look at whether Bard admitted any certain warnings in those -- in the PerFix Plug, Ventralex and 3DMax devices?
MS. STOKES: I'm going to object to that.
I'm going to instruct you not to answer.
MR. JESSEE: Okay.
BY MR. JESSEE:
Q. Were you asked to look at whether the Ventralight ST was -- admitted any warnings from its labeling?
MS. STOKES: Same instruction.
MR. JESSEE: Okay. I'd just note that I disagree --

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THE WITNESS: I'm sorry. What was the instruction?
MR. JESSEE: -- with the --
MS. STOKES: Not to answer.
THE WITNESS: Okay. That's an easy instruction.
MR. JESSEE: I -- I disagree that this is -- just for the record, and obviously I -- I disagree that this is privileged, especially when we have in his report where it's asked what he was asked to look at.
I'm entitled to explore those -- what exactly he was asked to look at. And so we would reserve to -- I'm going to -- plan to raise this issue with the Court. And then we can, if we need to, reconvene.
BY MR. JESSEE:
Q. The next issue, Doctor, on whether Bard's marketing of the PerFix Plug and Ventralight devices was misleading, were you asked to look at it in any particular ways whether it was misleading?

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MS. STOKES: Objection. Form. "Particular ways." But --
THE WITNESS: And I'm not sure I understand the question.
But -- but -- but the answer is no. I -- no. I -- there was no -- this -- no. The answer is no to your question.
BY MR. JESSEE:
Q. Okay. And this report though contains your opinions as to in which ways Bard's marketing of the PerFix Plug and Ventralight was misleading?
MS. STOKES: Objection. Form.
THE WITNESS: Including my testimony here today.
BY MR. JESSEE:
Q. Okay. And what about -- going back to that previous point, 9B, have you included in your report all the ways you believe that Bard admitted warning -- all the warnings -- let me strike that and start over.
Have you included in your report all

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of the warnings that you believe Bard omitted from the labeling in the PerFix Plug, Ventralex and 3DMax devices?

MS. STOKES: Objection. Form.

THE WITNESS: If you include the report and my testimony here today, yes, I've tried to do that.

BY MR. JESSEE:

Q. With the -- well, I -- and I want to know just about the -- focus just on the report.

Have you included in your report, as we sit here today, the opinions you have on any warnings that were omitted from the labelling of the PerFix Plug, Ventralex and 3DMax devices?

MS. STOKES: Objection. Asked and answered.

THE WITNESS: Well, you'd have to take into account my testimony today. I mean in order --

BY MR. JESSEE:

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Q. But -- I know. My question though is not about the -- I'm just wanting to know just about the report.

Have you included -- is there -- in the report, can you show me a page -- is there any other opinion, as we're sitting here right now, this point in time, that's not in here on the warnings?

A. We -- we discussed --

MS. STOKES: Objection. Form.

THE WITNESS: We -- we discussed things this morning.

BY MR. JESSEE:

Q. About warnings that you think should have been in these -- the labeling for these devices?

A. Yes. And we -- we just -- we just spent time discussing, for example, the MSDS issue. And Phillips had a -- a -- a warning that said "do not use." And --

Q. And so you're offering an opinion that --

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A. Wait. Can't I just finish my answer?

MS. STOKES: Yeah. Let him finish.

MR. JESSEE: Sure.

THE WITNESS: Right. So Phillips had a -- I guess two things. As I understand it, Phillips had the issue of -- that it had identified of oxidative degradation and had a do-not-use warning in its MSDS.

So that is a -- and that was on polypropylene. It was -- wasn't the only supplier over Bard's history. But it was one of the suppliers. And that went in -- to best of my knowledge, into these devices.

And having become aware, through Dr. Tillman, of the MSDS issues, that -- that potential safety hazard of that degradation and therefore do-not-use would rise to that potential safety hazard should have been warned about.

So that wasn't in my report as such. And that's what we talked about earlier this

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morning.

BY MR. JESSEE:

Q. Which devices -- can we agree that your report is focused primarily -- your opinions in the report and what you were asked to look at were focused on four devices: the PerFix Plug, Ventralight, 3DMax and Ventralex?

MS. STOKES: Objection. Form. Mischaracterizes.

THE WITNESS: Yeah. So you've got to be a little more specific. There's different versions of Ventralex. Then -- and we're talking about Ventralight ST. So -- in certain portions. So just -- there's various devices. So the report covers the devices that -- that are covered.

But obviously those devices are made out of material that Phillips supplied. And whatever warning -- whatever potential safety hazard that that raised, I mean, should obviously be warned about.

BY MR. JESSEE:

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Q. All right. Which of those devices that are referenced on Page 3 were made out of the Phillips Marlex polypropylene material?
A. So I have to -- I -- I don't want to testify on supply chain here. Because I think there are two -- two manufacturers over time at least. And the documentation that I saw certainly focused on the 2007, 2008 -- the documents about -- between Phillips and its -- and what was told to Phillips. I saw those documents. And those primarily focused on the 2006 to 2008 period.
So I'm only aware of -- you know, obviously with devices that were used later. And I'd have to go back and check the actual supply chain.
But whichever devices used whatever those warnings were, that's what should attach.
Q. Can you name -- tell me one of the devices that's listed on this page of your report that uses Marlex polypropylene?
A. What --

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MS. STOKES: Objection. Form.
THE WITNESS: Certainly Ventralex -- my understanding was the PerFix and Ventralex.
I'd have -- I'd want to double-check some of this. The -- the name changed to -- to Bard Mesh at certain times. And there -- there were different names attached, as you're well aware.
BY MR. JESSEE:
Q. What about Ventralight; does that contain Marlex polypropylene?
A. I -- I -- I can answer that question if you give me a minute.
Q. Well, Doctor, why don't we wait, and we'll come back to, and you can look at a break if you want to look into that.
A. I have -- I mean that -- that's just -- I mean I -- I'm happy to answer that question. Just give me a minute. And if you don't want me to answer it, that's fine. But I'm happy to answer --
Q. Okay.

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A. -- that -- that question.
So your specific question?
Q. Does Ventralight --
A. That's right.
Q. -- contain Marlex polypropylene?
A. Yeah. Let me just give you exactly the answer to that question. One second.
MR. JESSEE: And if it's going to take you a second, it's fine. I might go use -- let's -- let's go off the record for one second, please, and...
THE VIDEOGRAPHER: We are going off the record.
The time is 10:29.
(A short recess was taken.)
THE VIDEOGRAPHER: We are going back on the record.
The time is 10:33.
BY MR. JESSEE:
Q. Doctor, before we went off the record for a couple minutes, you were -- I had asked about whether Ventralight contains Marlex

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polypropylene in there.
And during that time you've been looking at your computer.
And I didn't ask you about this earlier, but what -- what exactly are you looking at on your computer?
A. I'm looking at the 510(k).
Q. Okay.
A. And I'm looking at specifically the 510(k) for Ventralight ST. And during break -- there are two 510(k) numbers. So I asked counsel which one. He wasn't sure. But I'm looking at the 510(k) application for Ventralight ST.
Q. And do you know what type of polypropylene Ventralight ST uses?
A. So I just looked at the materials. And from my -- I can't tell that from the poly -- from the discussion in certain sections of the report. It just uses the word "polypropylene." It doesn't identify the supply chain.

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I searched for the word "Marlex."
And I did not see the word "Marlex" in here.
So we'd have to go back to -- so the answer is
I -- I can't determine that from the 5 -- from
portions of the 510(k) that I looked at so far.
Q. Okay. And as we sit here today
right now, you can't -- you don't know whether
or not Marlex polypropylene was in the --
A. Not -- I mean I --
MS. STOKES: Objection. Form.
THE WITNESS: I'd have to go -- I --
I -- the answer is I -- not off the top of
mind. I mean it's not the -- a fact that I --
I may have it in certain sheets.
Actually, why don't -- just -- I
don't want to waste time.
MR. JESSEE: Yeah.
THE WITNESS: But I mean I -- if
you'd just hand me my Ventralight section
behind. Give me one more section --
MS. STOKES: Sure.
THE WITNESS: -- and see if I can

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get -- just give me Ventralight.
Let me see if I can give you the
answer. Again, this has the 510(k). And --
and let's just see if it identifies -- it just
uses the word "polypropylene monofilament used"
and then a knitted mesh with additional PGA
fibers added to the fill in the interlay --
hold on one second.
Manufacturer, Bard Shannon. I don't
see -- let me make sure, see if there's another
sheet.
It just says -- give me one more
second. It just uses the word "polypropylene."
It doesn't -- "polypropylene monofilament" is
what's told to FDA --
MS. STOKES: Okay.
THE WITNESS: -- in -- in this -- in
this part of the 510(k).
BY MR. JESSEE:
Q. Let's look back at your report,
please.
A. Sure. Of course.

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Q. And same page, on Page 3, where
the -- the issues you were asked to look into.
A. Yes.
Q. The -- on that number -- on
Paragraph 9E, you talk about design control
requirements for Ventralex with PET ring and
Ventralex with PDO ring. And you talk about
that in your report. We'll get into that.
Did you look at the design control
requirements and Bard's compliance with design
control compliance -- excuse me -- design
control requirements for any of the other
devices that you reviewed?
MS. STOKES: Objection. Form.
THE WITNESS: I'm sure I did. I
mean I -- it was -- it's part of the -- I'm
sure, in studying this, I -- I certainly looked
at the design history files.
I'm -- I'm not sure I got to a stage
of an opinion on that.
BY MR. JESSEE:
Q. Okay. Well --

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A. But -- but I -- but I certainly
looked at -- whenever -- whenever you have a
design history file, you didn't always identify
it as a design history file. Sometimes they
were called technical files. I mean sometimes
they were -- you know, in different places.
But I -- I certainly looked at the
design history files of a range of devices.
Q. Right.
And my -- my question is not whether
you looked at them.
But in -- in your report, there's
not opinions about the design history files or
the design control requirements related to
PerFix Plug, Ventralight or 3DMax.
Is that fair to say?
MS. STOKES: Objection. Form.
Mischaracterizes.
THE WITNESS: Yeah. We got to look
at individual paragraphs. We certainly talk
about audit reports, like Quintiles and Post.
And they have applicability. And even 483

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audits, they have applicability beyond any one device.

So again, I would use these questions for sort of sign posting, as my editor would -- my late editor, who tragically just died, would say to give you some sense of what I'm doing. But you got to read each paragraph and my testimony here today.

I wouldn't -- don't -- don't view this as -- as -- as sort of -- you've got to read the whole report, read all the testimony. And that -- that's where you -- don't -- don't just read these as the -- the actual precisely specific thing. It's only addressed in the report. These are -- these are questions, but there's a whole report here, and there's testimony.

BY MR. JESSEE:

Q. Right. And there's conclusions in the report.

And there's no -- in the Conclusion section of your report, you don't talk at all

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about the design controls for PerFix Plug, 3DMax or Ventralight.

A. I -- I -- I --

MS. STOKES: Objection. Form.

THE WITNESS: I -- I -- I take that. But on -- you know, there may be discussions of design stuff and the -- the -- the Quintiles audit or other things that may be discussed in the body of the report that could have relevance.

But you're -- you're correct. I tried to -- it tries to focus. But just don't -- read it -- read the report as a whole and the testimony as a whole.

BY MR. JESSEE:

Q. Let's switch gears a minute, Doctor. I want to talk about your work at the University of California San Francisco.

A. Sure.

Q. And we -- we talked briefly about it earlier, that you were the dean for a period of time; and then since then you've been a

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professor of pediatrics and of epidemiology and biostatistics.

A. Correct.

Q. Are you teaching at all in either of those positions?

A. Yes.

Q. In which one of those?

A. I'm teaching in epi.

Q. And what is that -- what do your teaching duties consist of?

A. A small group -- I have a upcoming small group on causation, et cetera, epidemiology.

Q. Okay. And is that -- is it in a classroom setting?

A. Yeah. Will be. Yeah. It's small group sessions with -- with medical students. Medical school teaching is not exactly what --

Q. Sure.

Not quite like law school, right?

A. No. It's not -- it's -- it's different.

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Q. The -- in the -- when you're -- and that's something -- have you have been teaching there for a while then?

A. On -- on and off. You know, there's a faculty of several -- about -- I mean in the thousands. And there's only 150 medical students a year. So there's many more faculty than there are student.

So at different years and different times, I do different things. Now I'm doing -- you know, I've been -- I've been asked to do the causation and stuff like that and -- and will do that.

Q. Are -- are you involved at all in any clinical studies that take place at UCSF?

A. Not --

MS. STOKES: Objection. Form.

THE WITNESS: Not currently. I was. I was head of the GCRC. So I was principal investigator of everything. I was -- I was the principal investigator of the GCRC through -- certainly through, my guess, what, 2007, 2008.

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But -- I -- let me -- let me leave it at that.
Q. And that -- that -- okay. Let me withdraw that.
Are you in -- have -- are you involved -- currently involved in any clinical protocols?
MS. STOKES: Objection. Form.
THE WITNESS: So I'm involved -- only to the extent -- I mean I -- the -- at UCSF are you asking?
MR. JESSEE: Yes?
THE WITNESS: Or are you asking on company stuff?
MR. JESSEE: UCSF.
THE WITNESS: UCSF I am not. I mean I am -- I am focused primarily on my research. I have a book coming out next -- what month is this are we? -- end of March. So I focused on my research.
BY MR. JESSEE:
Q. What -- what's that book on, what topic?

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A. It's --
MS. STOKES: Form.
Is that confidential? Can you talk about it?
THE WITNESS: Yeah. He's not going to -- he's not --
MR. JESSEE: If you don't want to, that's fine. May --
THE WITNESS: I mean I'm happy to -- to break and --
MR. JESSEE: That sounds good. That's fine.
THE WITNESS: And -- and -- and --
MR. JESSEE: I -- I didn't mean --
THE WITNESS: And -- and -- and --
MR. JESSEE: -- to ask you --
THE WITNESS: And I think I --
MR. JESSEE: I was just curious.
THE WITNESS: I probably owe you a --
THE REPORTER: I still need you guys to just one at a time, please.

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MR. JESSEE: All right. My -- sorry about that.
BY MR. JESSEE:
Q. Doctor --
A. Happy to tell you at the break.
Q. All right. Doctor, are you familiar with UCSF's Center For Hernia Repair and Abdominal Wall Reconstruction?
A. I am not in that department. I may be -- I may be aware of it, but I am not intimately aware of it.
Q. Okay. Do you know who Dr. Hobart Harris is, who's the chief of general surgery at UCSF Medical Center?
A. Certainly.
Q. He's someone you worked with for a long time?
A. I do.
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. Have you talked with Dr. Harris about hernia mesh at all?

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MS. STOKES: Objection. Form. Vague.
THE WITNESS: No. And I deliberately did not.
BY MR. JESSEE:
Q. And why is that?
A. Because I -- I wanted to -- I didn't think it would be appropriate. I wanted to stay with the record that was before me. And I didn't want to go extra -- outside of that record. I mean I could, but I did not.
Q. With Dr. Harris, is he -- he's someone who you've interacted with during your time at UCSF?
A. Yes.
MS. STOKES: Objection. Form.
THE WITNESS: Yeah. Yes.
BY MR. JESSEE:
Q. You're -- you're aware that at UCSF they -- the surgeons there like Dr. Harris implant hernia mesh to treat hernias, correct?
MS. STOKES: Objection. Form.

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Assumes facts.
THE WITNESS: Yeah. I'm -- I'm not going to -- I -- please let Dr. Harris testify what he does. I -- I can't testify to what Dr. Harris does.
MR. JESSEE: Okay. And I'm just -- all right.
I'll show you -- we'll go ahead and mark as an exhibit -- we are now at 18.
(Deposition Exhibit 18 was marked for identification.)
BY MR. JESSEE:
Q. Doctor, have you ever looked at the UCSF surgery web site?
A. I have.
Q. Okay. And you see that this is from actually the Center For Hernia Repair and Abdominal Wall Reconstruction portion of the web site.
MS. STOKES: Just going to object to foundation on this document.
BY MR. JESSEE:

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Q. And, Doctor, you can see at the bottom of the first page of the web site where I got this from, the date.
A. I see it.
Q. This one is -- at the top it says "UCSF Department of Surgery."
Do you see that?
A. I see that.
Q. And then it talks about laparoscopic ventral hernia repair?
A. That's what it says.
Q. And the last sentence of the first paragraph, when talking about the procedures performed here, says: "While viewing the monitor, the surgeon uses instruments to carefully repair the hernia using synthetic mesh."
A. I see that.
Q. Do you see that?
And I mean -- so, if I understand you, you didn't know one way or another whether hernia mesh was being used at UCSF prior to

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looking at this?
MS. STOKES: Objection. Form.
THE WITNESS: I -- I -- I --
MS. STOKES: Misstates.
THE WITNESS: -- would not want to testify who uses what where. It's a very general statement. Even the terms "mesh" is a very general statement. I mean the surgeons can testify what they use. And there will be surgeons that testify. They will testify. I can't -- I'm not going to testify what they use. You can -- you can ask them questions.
BY MR. JESSEE:
Q. Well, and I -- I can -- I'm -- I'm entitled to ask you questions that you -- about what your knowledge is.
And I just want to know do you have knowledge -- do you know whether hernia mesh is used in the majority of hospitals in the country?
MS. STOKES: Objection. Form. Outside the scope. Calls for speculation.

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Go ahead.
THE WITNESS: Yeah. So I don't have the -- I mean I don't -- I don't have epidemiological data that I reviewed here that would tell me again -- I -- I -- your question's so general. What kind of hernia? Where? At what point in time?
I've reviewed certain documents. But I don't -- I can't give you the epidemiological data. I don't know the studies to tell me which hospitals use what for what purposes at what points in time. I just don't have that data.
BY MR. JESSEE:
Q. When you were at Yale as the dean of that medical school, were they using synthetic hernia mesh at that points?
MS. STOKES: Objection. Form. Vague. Calls for speculation.
Answer if you can.
THE WITNESS: I --
MR. JESSEE: And I would just --

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object to form is fine. The speaking objections -- I've let it go for a while now, but they're completely improper.
MS. STOKES: Actually, CMO 22 specifically states that we can state the basis. So I would advise you to read the CMOs in this --
MR. JESSEE: And -- and I've read it. And we're -- that's fine.
BY MR. JESSEE:
Q. Doctor, I -- I don't mean to -- please go ahead. And I'd be happy to re-ask --
A. Yeah.
Q. -- too.
A. I mean my -- my suggestions are -- my -- my -- my answer is -- I mean I would -- I don't believe I have had -- I can't recall any conversation I have had with my colleagues in the department of surgery at Yale what hernia mesh they had to answer that's question precisely. I don't recall any conversation.
Q. Well, and I'm not asking about that

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even what hernia mesh but whether there was hernia mesh in general being used there.
A. I -- I --
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. Do you know one way or the other?
A. I -- I didn't -- I have not had any specific conversations. So I would be -- that I can recall that answers that question.
I mean I certainly am aware that hernia mesh has been used. I -- I -- I recognize that from our -- from the record here. But I don't want to testify what the views are and what they used. They should testify to that, right?
Q. You're certainly not critical of surgeons who use hernia mesh to hernia repair --
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. -- hernias, correct?
MS. STOKES: Objection. Form.

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Argumentative. Vague.
THE WITNESS: So for what device and what point in time?
BY MR. JESSEE:
Q. Talking --
A. What -- what -- what -- what -- what --
Q. -- currently as we sit --
A. Any hernia mesh, your question --
Q. Synthetic hernia mesh.
MS. STOKES: Same objections.
THE WITNESS: In -- in any -- any use? Anywhere in the body? In cancer surgery? In hernia surgery?
MR. JESSEE: I -- I --
THE WITNESS: Intraabdominal? Just you -- I mean --
BY MR. JESSEE:
Q. In -- to repair a hernia anywhere.
MS. STOKES: Same objections.
BY MR. JESSEE:
Q. Do you have criticisms of doctors

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that use synthetic mesh to repair a hernia?
MS. STOKES: Same objections.
THE WITNESS: I don't -- I didn't come -- it's the almost like your question about FDA to some extent.
I'm -- I'm happy to talk to you about the consensus statements on the use of hernia mesh. I've studied those. But I'm not here to level any -- and I think it would be inappropriate to be talking about criticisms of individual doctors or doctors using certain things.
I'm happy to talk about the consensus statements and the field in general.
BY MR. JESSEE:
Q. Do you know what Bard hernia mesh products are used at UCSF Center For Hernia Repair and Abdominal Wall Reconstruction?
MS. STOKES: Object to form. Calls for speculation.
THE WITNESS: I -- I could go in -- into the record and may be able to find the

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ordering, I mean, on the record. But I didn't see any documents in the record that specifically related to that.

BY MR. JESSEE:

Q. Did you --

A. And -- and -- and I'm not sure that -- again, with all due respect, Counselor, you're -- you're far away from -- I'm happy to talk about the regulation of these devices and the FDA regulation of these devices and the warnings on these devices. But -- and that's why I'm here.

If you want to talk about UCSF hernia's department, call them. I mean I -- I'm not -- I've -- I've stayed with the record. And I've tried to stay within the general framework of F -- the interface between regulation and these devices.

And you're asking me what individual surgeons are using. I mean I've looked at some of the medical records, I mean, again, in this case, just briefly, just to have some sense of

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them.

But I don't -- I'm not going to be offering case-specific kinds of stuff.

BY MR. JESSEE:

Q. Well --

A. That's for the surgeons.

Q. And we'll get into those medical records. Because I didn't see those in your reliance list.

But the -- as far as -- are you offering opinions on the risks and benefits of hernia surgery?

MS. STOKES: Objection. Form.

THE WITNESS: No. I -- I -- I think in the -- again, to -- to the extent that there's issues of safety and effectiveness as they meet the definition of -- in the Federal Food, Drug, and Cosmetic Act, I'm happy to deal with that.

In some global sense of whether the -- I'm happy to discuss -- so I understand -- and I understand what the general

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consensus is and where it's moving, happy to discuss that because I've looked at that.

The -- at different points in times outside of the regulatory interface between surgery and -- and the regulation, I think it's probably best to let others talk about it in the more abstract sense of what the risks -- what the surgeons -- there will be surgical experts, I believe, who talk about that.

BY MR. JESSEE:

Q. Okay. So the surgeons will cover those topics?

Or -- or --

A. I -- I --

Q. -- do we need to you them today? I'm just trying to --

A. I -- I --

MS. STOKES: Objection. Form.

THE WITNESS: I'm happy to talk about -- you know, there certainly is the movement -- if you -- you look at the latest consensus guidelines, the European guidelines,

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the Hernia Society guidelines, what the role of -- for example, preformed three dimensional -- I mean plug-type -- for example, European Hernia Society doesn't recommend using plug-type, as I understand it.

But again, I think the surgeons are probably better off talking about that. But as -- if it interfaces the regulatory context, happy to discuss it.

BY MR. JESSEE:

Q. Okay. And I'm still just trying to figure out what interfaces the regulatory complex [sic].

So let's look back at this document that I put in front of you.

A. Uh-huh.

Q. Exhibit No. -- is it 19?

A. 18.

Q. 18. Thank you.

MS. STOKES: It's 18.

Same objections with this document.

BY MR. JESSEE:

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Q. And --
MS. STOKES: Foundation.
BY MR. JESSEE:
Q. -- if you look at the section that's titled "Potential Complications."
Do you see that, Doctor, bottom of the page?
A. I do there.
Q. And it states: "Surgery to repair a ventral hernia is generally safe, and complications are uncommon."
You agree or disagree with that statement on the UCSF web site?
MS. STOKES: Objection. Form. Argumentative. Outside the scope. This document is -- lacks foundation.
Go ahead.
THE WITNESS: Yeah. I -- I don't think it -- that's not -- I mean if the -- I'm happy to talk about the IFU and promotional materials and -- in the FDA context, in the materials that FDA has looked at, I mean, or

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would be subject to that -- that scope.
This is -- this is not the IFU or the company's promotional materials. So I mean that certainly is not a statement that would appear in the IFU, or FDA would generally allow a statement like that.
BY MR. JESSEE:
Q. Are you offering an opinion in this case that the Ventralight ST risks outweigh its benefits?
MS. STOKES: Objection. Form.
THE WITNESS: So I -- I -- I have a very specific opinion on Ventralight and -- about misleading claims, about the complete healing period, right?
And I think that was miss -- those were misleading in the promotion. To make the claim that the -- the synthetic polymer, the Sepramesh -- the Sepra coating lasts for -- and protects for the complete healing period, that is a misleading -- that's my opinion on -- on Ventralight.

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And to the extent that there should be -- as we've talked about the MSDS earlier, I mean to the extent that there are warnings in there, that -- that would also be related.
But I'm not talking -- in general, again, happy to discuss -- I'm happy to discuss the risk-benefits as they relate to the regulatory and to -- to those -- to those claims.
So to the extent that -- to the extent that Ventralight was used intraabdominally, and there is not evidence that that claim -- that claim is misleading, I think there's concerns about the risk-benefit equation without human trial clinical trials that shows that it actually lasts for -- I mean -- I mean the -- the -- the Sepramesh works and the Sepra film coating -- the ST coating -- sorry -- for the polypropylene does protect.
Without -- without better human trials, I'm not sure that the risks are

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acceptable in light of the benefits. And -- but that's in the FDA regulatory context.
BY MR. JESSEE:
Q. Well, and you just said, "I'm not sure that."
I mean do you have an opinion, as you sit here today, that the risks outweigh the benefits of the device, or is that a topic that you're not opining on?
MS. STOKES: Objection. Form. Misstates.
THE WITNESS: So what I would opine on is that, again, going back to -- again, in the regulatory context -- let me just check one thing, if I can.
Sorry. Let me just pull it. I apologize. Make sure I...
So to the extent that we're -- we're talking about Ventralight ST; is that --
MR. JESSEE: Uh-huh.
THE WITNESS: -- fair?
So the -- to the extent that

Ventralight ST relied upon for its substantial equivalence, right, the Bard Composix, which relied upon Marlex and Gore-Tex --

THE REPORTER: I'm sorry. A couple of words were missed because there was interference with a cell phone.

So "which relied upon"?

Sorry for the interruption.

THE WITNESS: -- the -- the Bard Composix and the Marlex Gore-Tex.

I don't think one could conclude -- because these are not -- these raise new questions. Without human trials, I don't know how you can get to the market without Ventralex ST.

And without human trials, I don't know how you can say the risks are acceptable in light of the benefits, because that was never done -- this was approved through substantial equivalence.

BY MR. JESSEE:

Q. And I'm talking about, as we sit

here today, there's certainly been clinical trials on the Ventralight as -- in here in 2020, right?

MS. STOKES: Objection. Form.

THE WITNESS: Not -- not that's passed S -- FDA muster.

BY MR. JESSEE:

Q. You don't -- so none of the clinical trials to date here in 2020 have passed FDA muster, is your opinion?

A. So I'm happy to go through the --

THE WITNESS: Can you hand me my Ventralight ST.

BY MR. JESSEE:

Q. And so, Doctor, are you --

A. Sir, just -- just hold -- just -- let me answer your -- your question. Let me just...

MS. STOKES: I'm going to object to the form of the question.

THE WITNESS: Yeah. So -- so human studies that would show safe -- the risk are

acceptable in light of the benefits, human clinical trials on Ventralight ST were not done that were submitted to the FDA to support, I mean, its marketing. That I am sure of. Okay?

BY MR. JESSEE:

Q. Yeah. And that wasn't my question.

A. Adequate and well control -- no adequate or well-controlled clinical trials that support that Ventralight ST -- that support the risks are acceptable in light of the benefits.

BY MR. JESSEE:

Q. And, again, not my question.

2020 is what we're talk about now.

Have you reviewed the clinical literature on Ventralight ST up to 2020?

A. I -- I --

MS. STOKES: Objection. Form.

THE WITNESS: I have -- I have looked sub -- at a lot of the clinical literature. And I have focused specifically on the --

Can -- do me a favor. Could you hand me my Ventralight ST big chart.

BY MR. JESSEE:

Q. Doctor, if you wouldn't mind, I want to make sure I just know what exhibit number we're looking at.

A. I am happy to do this. So I have here -- this is the Ventralight ST.

MS. STOKES: Exhibit 15.

THE WITNESS: Yeah. This is -- to answer your question, this is Exhibit 15, right?

And I don't -- let me just take a look at this.

BY MR. JESSEE:

Q. And just so I know, can you just tell me what this table is that you are looking at?

A. So these are -- these are studies that are done on Ventralight ST that I see, as referenced in the record -- and let me just go back for a second.

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And I see none of these studies in humans that establish risks acceptable, in light of the benefits, that were part of the FDA record.

Q. Doctor, is your opinion that the Ventralight ST should be removed from the market?

MS. STOKES: Objection. Form.

THE WITNESS: My view is that it was -- that it was approved as substantially equivalent and that that was a -- it is not substantially equivalent in that chain, because, as we talked earlier, the Composix, the Marlex, and the Gore-Tex raised new questions.

It was not substantially equivalent. So it got on the market through the substantial equivalence mechanism. It should not have gotten on through that mechanism, and it should have had human trials that support the safety and effectiveness, because it's -- there's no way you can say this doesn't raise new

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questions of safety and effectiveness.

BY MR. JESSEE:

Q. Doctor, I will try it again. 2020, is it -- right now, is it your opinion that they -- the Ventralight ST should be removed from the market, either by the FDA or voluntarily?

MS. STOKES: Objection. Form.

THE WITNESS: I don't see a basis that showed -- I see a major flaw in how this device got on to the market through the substantial equivalence process.

It was not -- it should not -- the reliance on Bard Composix that this relies on for its predicate chain was incorrect. And I don't see a basis for how it's on the market when it raised new safety questions.

It got on the market. We can go back and -- happy to look at that 510(k). I don't see all the issues raised by your company. We discussed whether FDA could have done a better job.

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The issues of what do you do once it is on the market and it's been on the market, but it shouldn't be on the market, because it doesn't have a -- obviously, it raised new questions. It was a whole new technology of putting this in the peritoneal cavity.

BY MR. JESSEE:

Q. And you're talking about the Composix device, right?

MS. STOKES: Objection. Form.

THE WITNESS: No. But I'm -- no. I'm talking about the Composix device -- well, I'm talking about the Composix device, just so there's no -- here we're talking about Ventralight.

BY MR. JESSEE:

Q. Right. So Ventralight's --

A. Let me finish.

Ventralight relied upon, in the predicate chain, Composix. That was key to its -- and Composix dealt with Marlex mesh and Gore-Tex.

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And that was never studied. It certainly was not studied in humans. There weren't adequate clinical trials for that.

If this doesn't hold, this rest doesn't hold.

Q. Doctor, the predicate device for the Ventralight ST is what?

MS. STOKES: Objection. Form. Vague.

THE WITNESS: So you have -- you can't answer your question, because you put it as the predicate device. There are multiple predicate devices, and they are all laid out here.

And I'm happy to be corrected. This is the best, you know -- I mean, I could put -- assemble these. You can see there are predicate devices. There are predicate devices, and there's predicate devices.

So you have this whole chain, but this whole chain got started because Bard said, Well, we can't put Marlex in the abdomen, and

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we have to find something to protect it. So let's come up with a new way to do that. And we are going to use -- we are going to say to FDA, Well, you take a little of Gore-Tex here, and you take a little of Marlex, right, that are new devices, the same as those, but it's not the same as those, because as the brochure indicated, no one ever put this stuff in the abdominal cavity before.

BY MR. JESSEE:

Q. When was the Ventralight ST cleared? Maybe that's one we can get a clear answer on.

A. Sure. It's in the report.

MS. STOKES: Object to that --

THE WITNESS: Hold on a second.

MS. STOKES: -- side comment.

THE WITNESS: We will let him make comments. That's fine.

Take this back. I have the answer right here. Why don't we take these back. Just give me my predicate chain book.

So the Ventralight ST -- the

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clearance date was 7-15-2010.

BY MR. JESSEE:

Q. And what's listed in the 510(k) submission for the Ventralight ST is the Sepramesh IP, several of those 510(k)s, correct?

MS. STOKES: Objection. Form.

THE WITNESS: I have it in front of me. We can go through and look at all the devices that are listed, but, again, the application can speak for the application.

BY MR. JESSEE:

Q. And, in fact, you can look at the predicate device on the FDA web site right now for the -- except for the Ventralight ST, can't you?

A. Right.

MS. STOKES: Objection.

THE WITNESS: But the -- but that would be misleading, because you have to look at the predicate device for that predicate device.

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BY MR. JESSEE:

Q. So the information on the FDA web site is misleading in that regard?

MS. STOKES: Objection. Form. Mischaracterizes. Argumentative.

THE WITNESS: If you want to understand the predicate device and how it is substantially equivalent to a pre-'76 device, which is what the law requires there are a number of chains.

And, therefore, if you -- that's what I tried to do. I am happy to take your version of it if you have a different one or Dr. Tillman has one in her report, but it's very common that these are all the predicate devices for the Ventralight ST to take you back to a pre-'76 device.

BY MR. JESSEE:

Q. How long had the Composix that you were talking about earlier -- that was in 1997, correct, when it was cleared?

A. Correct.

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Q. And the Ventralight, you just said, ST was cleared in 2010?

A. Correct.

Q. I think we can agree approximately 13 years that the -- these surgical meshes with ePTFE and polypropylene layers have been, at least that amount of time, implanted abdominally?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. That's a new device that is not the same -- gone on through the 510(k) process, yes.

BY MR. JESSEE:

Q. And how many clinical studies were performed on those devices during that 13-year period?

MS. STOKES: Objection. Form. Vague.

THE WITNESS: I have the record. I can give you the record. It's in the FDA device. And there are other -- if you look at my appendix, you can see other clinical

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studies.
BY MR. JESSEE:
Q. Is it your opinion the Ventralight ST was not substantially equivalent with the Sepramesh IP?
MS. STOKES: Objection. Form.
THE WITNESS: That's not my opinion, no. That would be -- my opinion would be that it would be -- it's not substantially equivalent to a pre-amendment device, which is the requirement.
You have to be substantially equivalent to a pre-amendment device. There is nothing -- there is no pre-amendment device I would -- I would tell you that looks like Sepramesh Ventralight ST.
(Deposition Exhibit 19 was marked for identification.)
BY MR. JESSEE:
Q. I'm going to show you Exhibit 19. This is another document from the UCSF web site.

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Did you know that there is a Ventralight ST clinical study going on at UCSF right now?
A. I do not.
MS. STOKES: I'm going to object to foundation and also calls for speculation. Form.
THE WITNESS: I do not know that.
BY MR. JESSEE:
Q. Have you ever expressed any concerns about hernia mesh to anyone at UCSF?
MS. STOKES: Objection. Form.
THE WITNESS: I certainly would encourage studies to be -- I mean, a study like this? I am all in favor of studies -- human studies. I think that's the way this should have been done from the beginning.
BY MR. JESSEE:
Q. That wasn't my question.
Have you ever expressed any concerns about any hernia mesh to anyone at UCSF?
MS. STOKES: Objection. Form.

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Vague.
THE WITNESS: I have no -- I have not talked to anyone since I have looked at the record and have formed my opinions. I have deliberately not done that.
BY MR. JESSEE:
Q. Even before you were hired for litigation, have you ever expressed concerns to anyone at UCSF about hernia mesh?
MS. STOKES: Objection. Form.
THE WITNESS: I didn't -- I didn't look at the record. I had no basis -- I wasn't involved in hernia mesh. I didn't study this. I had nothing to do with hernia mesh at UCSF. I had no opinions on hernia mesh. I had no dealings on hernia mesh before.
BY MR. JESSEE:
Q. So you had no experience with hernia mesh prior to the litigation. And so that's when you --
MS. STOKES: Objection. Form. Misstates.

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THE WITNESS: I didn't study this record. I didn't have -- I mean, I was asked to study the record and to look at the regulatory history, and I have done that.
BY MR. JESSEE:
Q. Have you ever expressed any concern about any hernia mesh product with anyone at the FDA?
MS. STOKES: Objection. Form.
THE WITNESS: I have had no discussion -- I have had no discussion with anyone at the FDA. I have not -- I mean, certainly, I had no discussion before, and I would not have any discussion now without telling -- I deliberately stayed away from talking to FDA.
BY MR. JESSEE:
Q. Have you spoken with anyone, outside of your attorneys who hired you, to express concern about hernia mesh products in general?
MS. STOKES: Objection. Form.
THE WITNESS: I have not had any

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conversation, outside of -- based on what I have -- what I have learned, with anyone.

Are you clearing me to have those discussions, based on the record, or am I under protective order?

BY MR. JESSEE:

Q. So, Doctor, do you know anyone who has been implanted with a hernia mesh device?

MS. STOKES: Objection. Form.

THE WITNESS: I have the medical records. Happy to go through the bellwethers with you.

BY MR. JESSEE:

Q. I am not talking about the plaintiffs in this litigation, the six plaintiffs.

Do you know anyone besides them who has been implanted with a hernia mesh device?

MS. STOKES: Objection. Form. Vague. Calls for speculation.

THE WITNESS: Sitting here, I would not -- nothing pops in my head and -- nothing

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pops in my head.

BY MR. JESSEE:

Q. As a doctor who treats patients, have you ever advised an adult patient that they should not have their hernia repaired with mesh?

MS. STOKES: Objection. Form.

THE WITNESS: I have never been asked that question. I mean, it is not something that I, you know -- it is not a clinical question that I have been asked.

BY MR. JESSEE:

Q. Okay. You don't --

A. I have never -- I have not -- I certainly have treated -- I mean, there are hernias in the pediatric kind of context all the time.

Back when I was practicing, the different kinds of hernias, diaphragmatic hernias, et cetera, that I certainly have consulted on, but I have not since -- not in recent times. I have not had those

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discussions.

Q. When you say in recent times, have you ever treated an adult patient -- a hernia in an adult patient?

MS. STOKES: I'm just going to object. First of all, this is outside the scope. And you are getting into confidential information between a patient and a doctor.

MR. JESSEE: Improper is the main objection.

BY MR. JESSEE:

Q. Doctor?

A. I don't recall advising anyone being presented with anything in the hernia context on adult. I do have some recollections in the pediatric context, but those were years away.

And, again, just so -- if I can make your life a little easier, Counselor, I'm happy to -- I'm talking from a regulatory context.

So when you asked me whether it should be on the market, you noticed I referenced back to whether there was

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substantial equivalence and whether there were human trials and adequate and well-controlled evidence of -- to support risks and benefits.

So I did it in the regulatory context. With regard to the clinical use, let the surgeons testify.

Q. Would it be fair, as to whether a specific device, the risk/benefit analysis for a specific patient, that's something that's outside of what you're offering opinions on?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. I don't -- I'm not going to be -- I mean, I asked for -- I have -- I'm not relying on -- I just don't want to, you know -- I want to have some context for what the case is about.

So, I mean, that's why I know something about, you know, the devices that were used, but I'm not going to be case specific, Counselor. You can ask the surgeons. Others will testify.

Use me in the global sense. I mean,

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I can -- if you want to ask about an op report in one of the bellwethers, we can discuss it, but that's not where we should be spending my view -- my time.

BY MR. JESSEE:

Q. I'm trying to just figure out what your -- opinions you're going to offer at trial so I know, but it sounds like though you're not going to offer any opinions on the specific plaintiff.

A. Correct.

Q. Right. And you mentioned these medical records. I didn't recall seeing those in your reliance list or in your report, a reference to those.

And that's just -- so you're not -- it's not relevant to your opinions, those medical records?

MS. STOKES: Objection. Form.

THE WITNESS: They give me some -- I asked counsel for them just so I have some context, but I'm not -- it would be much

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better -- I mean, if the judge or you ask me a basic -- what's a hernia, I will be happy to answer to the court.

I mean, if you ask me whether intraperitoneal was used and it's tied to the IFU and what was used over time, I can answer those questions, I mean, as a doc, but whether this -- in this patient, this was the right device, others will testify.

BY MR. JESSEE:

Q. Okay. And would it be fair to say others besides you would testify as to whether a specific Bard device caused an injury to a specific plaintiff?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. I think that's right. I don't want to get into causation -- specific causation on a specific patient. Surgeons will testify to that.

BY MR. JESSEE:

Q. Do you believe that hernia mesh devices in general should be banned from the

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market?

MS. STOKES: Objection. Form. Vague.

THE WITNESS: No. But you've asked me a very vague question. I mean, if you -- you should -- I mean, I think questions like that -- I mean, what kind of hernia mesh, where that hernia mesh, for what plane we are talking about, what kind of surgery we are talking about, that, you know -- certainly, flat -- you know, pari-peritoneal meshes, I have -- I have no issue, pari-peritoneal.

It's as -- and the original surgical mesh, as you know -- I mean, you know, there were meshes that were approved under my watch, and I don't see an issue.

It's when these meshes went to different places and different planes and different indications and were new and raised new sets of questions and risks. That's where I become concerned.

BY MR. JESSEE:

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Q. What specific hernia mesh devices do you think should be banned by the FDA?

MS. STOKES: Objection. Form.

THE WITNESS: I think any -- again, I have not issued an opinion on that. I'm happy to discuss -- I mean, in general -- in general, if there -- if a hernia mesh device went into -- raised new questions of safety and effectiveness and there weren't adequate human trials to answer those questions, then I don't think those devices should be on the market until those human trials.

Banning is a much more complicated question, and I have lived that. And, you know, sometimes something is on the market, and you leave it on the market, even though it shouldn't be on the market, because it's been on the market, and it becomes complicated, but that is a whole different story.

MR. JESSEE: And I will just move to strike after, "I have not issued an opinion on that."

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BY MR. JESSEE:
Q. Doctor, are you offering any opinions regarding the appropriate way to treat or repair hernias --
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. -- or is that something that the surgeons should talk about?
MS. STOKES: Objection.
THE WITNESS: Only in the FDA context. So if you want to talk about an indicated use or intended use, I am willing to talk about the intended use and whether that would be appropriate in the regulatory context.
What an individual physician, in his or her judgment, decides to do with a legally marketed product, I'm not going to judge, right, but I'm willing to certainly talk about the intended use and the indication for use and the scientific basis in the regulatory record.
BY MR. JESSEE:
Q. Do you intend to offer any opinions

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on the risks and benefits of nonmesh hernia repair procedures?
MS. STOKES: Objection. Form.
THE WITNESS: I think that's probably -- I think surgeons who have studied that should testify to that. So the answer would be, I will let others -- again, your questions are so general.
I mean, they should be, you know, for intraabdominal, for pari-peritoneal, inguinal. I mean, I think you have to ask those specific questions, but, in general, non -- I'm going to stay to the regulatory interface.
BY MR. JESSEE:
Q. Would that include not offering any opinions on the standard of care of any of the implanting physicians in these cases?
MS. STOKES: Objection. Form.
THE WITNESS: Be more specific when you say standard of care.
BY MR. JESSEE:

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Q. The standard of care -- well, you understand, from a physicians -- they have a standard of care that is expected of them in practicing and performing surgery?
MS. STOKES: Objection. Form.
THE WITNESS: Sure. I mean, I have studied -- I mean, I understand interstate law and common law. I understand what you mean, Counselor.
I think that there are certain -- I could conceive of you asking me a question, as it relates to the IFU, that may -- or the regulatory context and confronted with this device approved for this -- I'm sorry -- cleared for this or whatever in the abstract, how does that affect the standard of care, but, in general, unless it's in the FDA -- unless you are asking me a question about the IFU or the labeling or the promotional material, I'm not going to get into that. Just as -- it could abut is what I am raising.
BY MR. JESSEE:

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Q. Are you -- well, then -- so since I'm still not clear on the -- how you are defining and differentiating that, do you have any opinions -- standard of care opinions about the specific implanting physicians in the Johns case?
MS. STOKES: Objection. Form. Asked and answered.
THE WITNESS: I'm not going to -- as a general basis, unless you ask me something specific about the label or the promotional materials, as it relates to that physician, I'm not going -- I have no opinion.
BY MR. JESSEE:
Q. Okay. Any standard of care opinions of the implanting physician in the Stinson case?
MS. STOKES: Objection. Form. Asked and answered.
THE WITNESS: Again, you can take the same answer in each one of those cases. Save your time. I mean, I --

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BY MR. JESSEE:
Q. I appreciate that.
We may have covered this earlier. And if I did, I apologize, but you are not offering legal opinions in this case, correct?
A. I can't, and I won't. Now, I am happy to explain to the Court, to the extent the Court would like, the FDA regulatory framework.
And as that's based on statute, right, you know, I leave it to the judge, but certainly not on ultimate legal questions. I'm not going to do that.
I mean, the ultimate legal questions, but each judge can instruct me how, you know -- can I talk about the statute? I would think so. Can I talk about the appropriateness of conduct under the statute?
So those obviously have regulatory -- those are regulatory issues, but ultimate legal question, I would never want to get into.
Q. For example, you wouldn't give an

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opinion on the ultimate legal question on whether Bard is liable to any individual plaintiff, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Of course not.
BY MR. JESSEE:
Q. And same thing. You're not going to give an ultimate legal opinion that there is a design defect in a specific product, correct?
MS. STOKES: Objection. Form.
THE WITNESS: It depends on how the question is viewed. I mean, it depends on how you ask the question exactly, right?
So if it's the ultimate legal opinion for the jury, of course not. Whether there were adequate -- whether you followed adequate design controls, that's different than a design defect kind of question.
BY MR. JESSEE:
Q. Right. Exactly.
A. So I think we understand. It's the ultimate question I will certainly stay away

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from. And the judge -- you and the judge will instruct me how -- how far or what I'm allowed to go into in this regulatory construct. I understand that, but some of these have, you know -- they are regulatory questions.
Q. You are not offering any opinions on damages. We can agree on that.
A. Of course.
MS. STOKES: Objection.
BY MR. JESSEE:
Q. No opinions on the informed consent discussions between any specific plaintiff in this case and his physician?
MS. STOKES: Objection. Form.
THE WITNESS: I have great expertise. I have served on IRBs. I was in charge of -- if you show me a consent form, I'm happy to, you know, give you an opinion, but I have not specifically looked at -- I'm not intending to do that. I certainly could, but I don't -- I'm not planning to.
BY MR. JESSEE:

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Q. What is -- I want to look into your prior testimony. I believe it's Appendix B to your report. And so this would be Exhibit No. 2, I believe.
A. Let me just get my --
Q. And this is -- obviously, I know you have your own copies.
A. Hopefully, I have a --
Q. If not, we can --
THE WITNESS: Can you see if there is an appendix?
I have my schedules. I have my report. I thought I had a binder on -- actually, hold on a second. Give me one second. It may be in here. I thought I brought that.
BY MR. JESSEE:
Q. You have it?
A. I do, sir.
Q. I was looking for it for you.
And this is a list of your prior testimony that was served with your expert

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report.
Have you reviewed this?
A. I have. I have compiled it.
Q. Is there anything that needs to be added to this list of testimony since -- or I will just stop there.
Anything that needs to be added to this list of testimony right now?
A. I may have testified -- I have to check dates. I may have testified -- I think this was -- again, there is always a chance something is wrong. Something gets left off by accident.
I don't want to represent -- I think this is through the date of -- I think this is accurate as it stays here, but there is always a chance that something could get, you know -- I made mistakes before.
Q. Oh, sure. And I'm not suggesting anything. I'm just asking whether -- to the best of your knowledge, is this accurate, as you look at it?

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A. Yes. I think this is accurate, as it -- as it states -- this document states.
Q. And I understand that you were deposed in the opioid litigation last week, was it?
A. So this document -- that is what I was just going to -- I just looked at. This document is through November 26, and I believe I was -- the opioid legislation is here, but I was deposed in New York state, AG opioids, I think, a couple weeks ago.
Q. That was -- was that the last deposition you have given?
A. Yes, sir.
Q. Was that in January?
A. Yes. I believe so.
Q. Were you deposed at all in December 2019?
A. I don't have a recollection. I don't -- I don't remember dates. I'm sorry. I can remember so far two weeks back.
I -- there may have been a

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supplemental deposition. There was a short deposition of two hours in Essure. It's possible there was a secondary deposition.
Q. That's Essure?
A. That's on here.
Q. Okay.
A. It's on here, but I think there was -- there was two more hours. There was some additional materials. There was some additional issues that came up post.
Q. Okay. I want to walk through the list of prior testimony, certain ones, and I'm going to ask you about them, whether they were personal injury lawsuits involving a medical device or a pharmaceutical?
A. Sure.
Q. And so the first one is in regard to Risperdal?
A. Pharmaceutical.
Q. And that was a personal injury --
A. Yes.
Q. -- case?

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A. Well, there is a plaintiff. Let's just define personal injury. Some of these are multiple plaintiffs or whatever. They may have been aggregated cases. I just --
Q. Right. And my point --
A. I just want to make sure I understand your question.
Q. My question -- if you remember back to those tort classes in law school years ago, about whether the plaintiff is alleging an injury against a medical device or pharmaceutical manufacturer.
A. Yes.
Q. Okay. And would the same -- would the -- both the Wells v. Allergan and Drake v. Allergan be personal injury cases against a pharmaceutical manufacturer?
MS. STOKES: Objection. Form.
THE WITNESS: That was Botox. And I think Botox -- it may have been classified as a biologic. We'd have to go take a look.
It was Botox for seizures. So it

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was -- in developmentally disabled kids. So I am not sure how you want to characterize Botox as drug device. I have to go look.
BY MR. JESSEE:
Q. And for both of those cases, you were an expert for plaintiffs, correct?
A. Correct.
Q. And for the Risperdal, you were an expert for plaintiffs?
A. Correct. The vast majority of these, I will give you, to save you time. There are some defendant cases, but the vast majority are plaintiffs's cases.
Q. And would you agree that, in every personal injury case that you have testified, you have testified for plaintiffs?
MS. STOKES: Objection. Form.
THE WITNESS: No.
BY MR. JESSEE:
Q. What case -- personal injury case have you given testimony for the defendant manufacturer?

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MS. STOKES: Objection. Form.
THE WITNESS: I think if you look at these endoscopy cases, they're sworn expert statements. Don't hold me to them, but I believe Cordero was for the defense. We'd have to pull it up.
BY MR. JESSEE:
Q. And I actually did look at that Cordero one. This is a sworn expert statement that we're talking about, not testimony there, right?
A. I leave it to -- it says sworn expert.
Q. And it's a separate section of your --
A. I just want to make -- yes.
Q. And that was actually -- you mentioned Kessler a little earlier. I believe that was where you were asked to -- where you gave a sworn statement, rebutting a statement about what the Kessler rule was?
A. For the defense, if I'm correct.

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Right.
Q. Did you ever testify in a deposition in that case?
A. I don't think that I got called. I'm not too sure.
Q. Did you ever testify at trial?
A. I don't believe it went -- I don't believe, no.
Q. Any personal injury case where you actually testified at a trial or at a deposition on behalf of the defendant manufacturer?
MS. STOKES: Objection. Form.
THE WITNESS: A number of cases for defense, but I don't -- I don't think, if my memory serves me right, they were, quote, personal injury cases. There were a number of defense cases, but I don't believe personal injury.
BY MR. JESSEE:
Q. Okay. So, for example, when we have the pelvic -- C.R. Bard pelvic mesh litigation

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involving pelvic mesh, you testified for plaintiffs in that case, right?
A. And I was deposed by your colleague. And I did not testify at trial.
Q. Okay. And in -- did you rely on any of your documents, files from that litigation in your opinions here?
MS. STOKES: Objection. Form.
THE WITNESS: I don't -- there are -- the answer is no. I don't think I relied on that. Let me just give you a full answer though.
There are -- there are certain discussions of the statute, for example, that I may have used in that matter that I used in other matters that I -- I mean, defining Class II and defining Class III would be applicable.
I didn't rely on anything specific to that matter, but I may have -- I mean, if you pulled that report, we may be able to see something, I mean, in that report that matches this in general about device framework.

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BY MR. JESSEE:
Q. Sure.
A. I mean, I don't want to say it's boilerplate, but I think you understand what I -- hoping -- and I would go on record saying, hoping Ms. Cohen was going to depose me --
BY MR. JESSEE:
Q. I don't need to hear that.
A. Hoping that Ms. Cohen was going to depose me, I did, last night, I will tell you, look -- I only had the rough. I looked at her questions, I mean, in vaginal mesh, and it brought back fond memories.
Q. Well, I'm sure she will be glad to hear that, but --
A. So -- but I don't think that's -- that's not relying substantively.
Q. And your -- do you keep an active working file from your pelvic mesh?
A. I did not. I did -- I did have to search out that deposition again just to refresh, because I was hoping Ms. Cohen was

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going to come and ask me the same questions she asked me last time.
Q. I was really focusing more on like as far as corporate documents though.
A. No, no, no, no, no. I mean, with the exception of -- no, I don't. The only thing that -- again, just to be upfront, there could be some discussion of medical device regulation history that -- but, again, it probably predates even mesh.
So I don't rely on that, but, you know, I want to be consistent on what the framework is, but what happened there is not -- has nothing to do with -- I don't rely on what happened here.
Q. You didn't offer, in that pelvic mesh litigation, any opinions on the material safety data sheet, did you?
MS. STOKES: Objection. Form.
THE WITNESS: I did not.
BY MR. JESSEE:
Q. Looking back to your prior testimony

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list, SB versus Ortho-McNeil, Janssen Pharma, that would be a pharmaceutical personal injury case?
A. Just show me where we are.
Q. Right after that pelvic mesh, pelvic repair systems, five down.
A. That's Risperdal.
Q. And, again, you testified on behalf of plaintiffs?
A. Yes. I'm sure I did.
Q. And in regard to Yaz and Yasmin?
A. Pharmaceutical.
Q. You testified on behalf of plaintiffs?
A. Correct.
Q. In regard to Actos, products liability litigation?
MS. STOKES: Objection. Form.
THE WITNESS: Show me where.
BY MR. JESSEE:
Q. It is about halfway down.
A. That was a -- Actos was a -- I think

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it was -- it was -- it was -- it was combined MD. It would fit your definition of plaintiff. I believe it -- it's drug.
Q. And you testified on behalf of plaintiffs in that case?
A. Correct.
Q. In the Cabana versus Stryker case in California -- and this is about five further down.
A. That -- if my memory serves me right, that's medical device, but it could be medical device biologic, if I'm -- it's an infuse device, if my memory serves me right, which is a combination product, biologic and device.
Q. And you testified on behalf of plaintiffs in that?
A. I did.
Q. And Fosamax is a pharmaceutical litigation? You testified on behalf of plaintiffs?
A. Yeah. But that was just on

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preemption. That was -- which one is that? That's -- the New Jersey, yes, but that -- in California. That was limited to preemption.
Q. It was -- the underlying case was a personal injury --
MS. STOKES: Objection.
THE WITNESS: Yeah. But I didn't testify with regard to that liability. It was solely on the question of preemption under the statute. It was a lateral question.
BY MR. JESSEE:
Q. On that question of preemption that you testified on, you testified on behalf of plaintiffs?
A. Correct.
Q. In the -- in regard to DePuy Orthopedics, the Pinnacle hip implant litigation, that was a personal injury case that you testified on behalf of plaintiffs?
MS. STOKES: Objection. Form.
THE WITNESS: Medical device, yes.
BY MR. JESSEE:

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Q. We have Anders v. Medtronic in Missouri. I'm on the second page now, Doctor.
A. I think that's similar to the -- that was another infuse. That was infuse.
Q. So medical device on behalf of plaintiffs?
A. Medical device biologic, yeah.
Q. And in the Austin/C.R. Bard, that was an IVC filter case, I believe; is that correct?
A. Correct.
Q. And you testified on behalf of the plaintiffs?
A. Correct.
Q. In the -- in regard to Bard IVC filters products liability litigation, that's another IVC filter litigation, correct?
A. Yeah. This was -- this was an aggregated case, yes.
Q. And you testified on behalf of the plaintiffs?
A. As in Austin, I believe.

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Q. Zoloft litigation, that was a pharmaceutical personal injury case you testified on behalf of plaintiffs?
MS. STOKES: Objection. Form.
THE WITNESS: Yes. That would be correct. That's drug. It was a consolidated case.
BY MR. JESSEE:
Q. And the testosterone replacement therapy, products liability litigation, did you testify on behalf of plaintiff in that case?
A. I did. And that was device. Well, it's AndroGel. I'm embarrassed to say. I think it probably was AndroGel. I mean, it had components.
Q. What about --
A. It was a patch. It was a drug delivery device -- drug delivery system.
Q. Any of the next -- were all the next -- the next three cases that are listed here, were they all testifying on behalf of plaintiffs?

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MS. STOKES: Objection. Form.
THE WITNESS: I believe so. Some of these are state AG cases, like the next one.
BY MR. JESSEE:
Q. Which one is that?
A. The State of Texas. So these are -- there are a number of these cases where I have testified. So in the State of Texas, that was for the AG.
The People of the State of California, that was the recent -- I guess that was the verdict yesterday on mesh. I testified in that for The People of the State of California.
Q. And I know you gave a deposition in that case. Did you also testify live at trial?
A. Live at trial in mesh.
Q. And the --
A. It was a judge trial.
Q. -- Taxotere litigation, that's a case where you testified for plaintiffs both at deposition and trial, correct?

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A. Correct.
Q. And the opioid litigation, we discussed, but that's -- you're testifying on behalf of plaintiffs?
A. No. I'm testifying -- well, yes. So sorry. I'm testifying on behalf of cities and counties.
Q. In the -- in regard to Essure birth control, that would be -- you are testifying on behalf of plaintiffs?
A. Correct.
Q. In all of those cases that we just discussed, where they're personal injury cases and you're testifying on behalf of plaintiffs, have you ever given the opinion that the device, drug, or biologic labeling was adequate?
MS. STOKES: Objection. Form.
THE WITNESS: I don't believe -- I mean, in some of these cases where that has come up, I have given -- well, in some cases, for example, in the antitrust, I have gone back

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and looked.
And I believe there are -- depending on what section of the label I am looking at, I think I have said I don't have a problem. There have been times when I have said I don't have a problem with the label. I recall that.
Now, whether those were antitrust cases, I'd have to go back exactly, where I have said that, but I don't have problems with every section of the label.
BY MR. JESSEE:
Q. My focus is on the -- specifically on the personal injury cases, where you testified.
Have you ever said that the label for the drug, device, or biologic was adequate, and you had no criticisms of it?
MS. STOKES: Objection. Form. Vague. Compound.
THE WITNESS: I would want to go back and look. For example, in the New York opioid case that I just testified -- you know,

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I'm under oath. I just -- I don't want to misspeak here.
Did I -- I'm not sure I criticized -- I'd have to go back. Did I criticize the label in the -- what was it? The marketing that I criticized.
I apologize. I just -- I don't know --
BY MR. JESSEE:
Q. That's fine.
A. -- specifically.
Q. Are there any other ones beside the opioid litigation, where you are not sure about whether you criticized the label or not?
MS. STOKES: Objection. Form.
THE WITNESS: Sure. I know there was -- well, I would want to look at the trial testimony, I think, in some of these prograph cases, et cetera, Nexium cases. I'd have to go back and take a look.
BY MR. JESSEE:
Q. Can we agree that, in the vast

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majority of the cases we just discussed though, you did -- you were critical of the label of the drug or device?
MS. STOKES: Objection. Form.
THE WITNESS: I wouldn't want to make any general -- we'd have to go look at specific -- just because I'm under oath, exactly what I was critical of. It may have been the marketing. It may be the labeling. I just don't want to make any general statements.
BY MR. JESSEE:
Q. Well, can we agree that in each -- and we have the depositions, I think, or transcripts of most of these here, but would you agree that for -- in each of those cases, you were critical of either the labeling or the marketing of the defendant manufacturer?
MS. STOKES: Objection. Form. Asked and answered. Compound.
THE WITNESS: Yeah. I mean, I think I'm -- I am under oath. If you want to show me a specific case and we can look at the

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deposition and my testimony or the transcript, I would be happy to answer. I just don't want to lump things together.

BY MR. JESSEE:

Q. Can you tell me a specific -- one of those cases, as we sit here today, where you were not critical of the defendant manufacturer's labeling or marketing?

MS. STOKES: Objection. Form. Asked and answered.

THE WITNESS: I just said I -- for example, the opioid case. I'd have -- I just -- I mean, I can show you -- I just -- I think -- I don't think I criticized the labeling, but, again, I don't want to be -- I don't want to say that under oath, because I may -- there may have been a question, in ten hours of testimony, where I said something. So I would have to go back and review to be specific.

BY MR. JESSEE:

Q. Okay. So you can't tell me, as we

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sit here today, without going back and reviewing, that there's a specific case where you testified for plaintiffs and weren't critical of the labeling and marketing?

MS. STOKES: Objection. Form.

THE WITNESS: I mean, I tend to remember those, but I don't want to swear under oath until I confirm that. I'm happy to do that, sir.

BY MR. JESSEE:

Q. You are happy to do that?

A. I'm happy to go back and look specifically, but I'd have to review the transcript so we can be clear.

Q. Okay.

A. I just don't want to make a mistake.

Q. All right. Well, I'd appreciate that. That would be very helpful.

A. Happy to do that.

Q. And, Doctor, with the -- I've marked as Exhibit 5 the invoice that was given us today. I know we have a lot of documents that

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have been moving around up here.

A. Sure.

Q. Do you happen to have that handy?

A. It's in the pile?

Q. It should be. We marked it right at the beginning. So I'd be happy to help you, if you'd like. I think it might be under there probably.

A. It should be --

Q. 3, 4, 5.

A. There you go.

Q. Doctor, this is the invoice that's dated December 10th, 2019?

A. Yes.

Q. And it says via e-mail, and it lists two attorneys. And one is Parvin.

MR. JESSEE: And I apologize, but maybe someone can help me with the last name?

MS. AMINOLROAYA: Aminolroaya.

MR. JESSEE: Okay. Thank you.

BY MR. JESSEE:

Q. And Kesley Stokes?

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A. The L is silent.

Q. What was that?

A. The L is silent.

Q. Okay.

THE WITNESS: Is that fair?

MS. STOKES: Sure.

MR. JESSEE: I didn't know we would be going into this.

BY MR. JESSEE:

Q. So these are two of the attorneys for plaintiffs, right?

MS. STOKES: Except for the fact you mispronounced my name, but --

MR. JESSEE: Okay. I apologize.

THE WITNESS: Did I?

MS. STOKES: No, no, no. You didn't. He did.

MR. JESSEE: I apologize.

MS. STOKES: It's okay.

THE WITNESS: Kelsey.

MS. STOKES: You said Kesley. It's --

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MR. JESSEE: Oh, I did.
MS. STOKES: Yeah.
MR. JESSEE: Okay. I actually even knew that too. I apologize for that. I got thrown off.
THE WITNESS: I'm the Kessler. You are the Kelsey.
BY MR. JESSEE:
Q. Doctor, this is the invoice that was sent to attorneys for the plaintiffs in this litigation, correct?
A. Correct.
Q. And I understand though that your wife typically does your invoicing for you?
A. You read my depositions, or either that a lawyer has told you.
Q. I have read plenty of them, yes.
And that is still the case?
A. Yes. Exactly.
Q. And this looks like -- it says December 10th, 2019. Is that -- that's when it would have been submitted?

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A. Correct.
Q. And so it did count for your time up until that point?
A. Correct.
Q. And the amount of this, as we already mentioned, is $237,264.93?
A. Correct.
Q. And it notes below that the amount of hours, where it says 232.25 hours --
A. Correct.
Q. -- at $1,000 per hour?
A. Correct.
Q. And $1,000 per hour is the typical amount that you charge in serving as an expert in litigation?
MS. STOKES: Objection. Form.
THE WITNESS: It's been my standard fee for a decade or plus.
BY MR. JESSEE:
Q. There is certain litigations that you have testified in and not charged the party any money, right?

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MS. STOKES: Objection. Form. I mean --
THE WITNESS: You're going to make these attorneys --
MS. STOKES: Yeah. I don't think that's --
THE WITNESS: No, no, no, no. I'm happy to answer your question. I have testified pro bono for the State of California.
BY MR. JESSEE:
Q. I mean, that's public record too, right? You testified at trial.
A. I was asked the question, and it's in the transcript. And you have done your homework.
Q. But you are not doing that in this case. You are not testifying pro bono in this case.
A. No. Unfortunately, one can't do that all the time.
Q. And, Doctor, what were the -- you list here expenses in the amount of a little

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over $5,000.
What did those expenses consist of?
A. They were probably travel.
Q. Was your -- let me withdraw that and start over.
Keep in mind this is dated December 10th, 2019.
Was your expert report finished at this point in time? In other words, would this amount constitute all the amount you put into putting together the expert report?
MS. STOKES: Objection. Form.
THE WITNESS: Fair.
BY MR. JESSEE:
Q. So did you work on the expert report -- and I am just talking about the expert report itself -- at any point after this invoice was submitted?
A. No. Well, the expert report was signed December 4th, right?
Q. Yes.
A. So this is December 10th. So, I

mean, the expert report was served on December 4th.
Q. Okay. So would this --
A. Does that answer your question?
Q. Yeah, it does. And maybe I can ask a better one.
This accounts for all your time up to December 10?
A. Yes.
Q. And I know -- I can tell from the -- all the materials that you graciously brought here today and our testimony earlier that you have spent time on this litigation since December 10th, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Correct.
BY MR. JESSEE:
Q. How much time have you spent since December 10th?
A. I don't know. I don't know exactly. I mean -- I don't know exactly. You could -- do you want me to guess?

Q. Sure. And I won't hold you to it. If you can just give me a rough estimate.
A. Again, I have not compiled an invoice. So I'm just -- I mean, lit could be 100, 110 hours, but don't hold me to any numbers here.
Q. Okay.
A. Not including today.
Q. Right.
And for those 100 to 110 hours, whatever the amount is, and for today, you are being compensated for $1,000 an hour?
MS. STOKES: Objection. Form.
THE WITNESS: I will submit an invoice --
BY MR. JESSEE:
Q. Okay.
A. -- for that. Yes, sir.
Q. And I guess the point I was getting at, for your testimony today, it's $1,000 an hour as well?
A. Are you paying me?

Q. I think we're still discussing that, but regardless of who's paying you, does it change if I am paying you?
A. No, no. I promise you to give you and your colleague the same rate that I give everyone else, except for the State of California.
Q. The -- so would it be -- let me strike that.
Looking back to some of your older transcripts, I noticed that when Laurie deposed you in pelvic mesh, you were asked -- at that point, you had billed approximately $400,000 in that litigation? Does that sound about right?
MS. STOKES: Objection. Form. Do you have the deposition transcript to show him?
THE WITNESS: I'm not going to dispute anything you have read.
BY MR. JESSEE:
Q. And you read the deposition transcript.
A. I didn't get to that part.

Q. Okay.
A. I had a rough. I will admit I did it -- I mean, I was skimming her questions. So I didn't get -- I didn't see everything.
Q. In the IVC filter transcripts I looked at, I saw, at one point, you had billed $600,000 approximately in that litigation?
MS. STOKES: Objection. Form. If you have a document, show him.
THE WITNESS: Yeah. I don't remember a bill for -- I mean, again, I don't want to -- I don't remember a bill for 600. I'm not saying, cumulatively, over -- you put multiple bills together.
If you put multiple bills, maybe you can get to something. I don't remember a bill for 600,000. That would seem -- but over multiple times and this one, this one, this one, this one, I mean, it certainly could add up.
BY MR. JESSEE:
Q. The Taxotere trial, which was last

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year, right? The Taxotere trial was last year, I believe?

A. Yeah.

Q. 2019?

A. That's right.

Q. In the fall?

And in that case, you testified that over the course of your litigation work for plaintiffs, you made millions.

Do you recall that?

A. Yeah. I think the question was millions and millions. I said, one million -- millions is enough, I think, was the testimony.

Q. Right. You said -- yeah. That's exactly right.

A. I think that was a little bit of a redundant thing, I mean. So yes. I would -- I have made millions -- I have made millions of dollars in litigation.

I have made millions of dollars from my books. I have made millions of dollars from my private equity. So yes, I have made million

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of dollars.

Q. With regard to your litigation work for plaintiffs in personal injury cases, have you made over $10 million?

MS. STOKES: Objection. Form. Calls for speculation.

THE WITNESS: You know, I don't -- I don't know the answer to that question. I certainly have made millions of dollars. I just don't know what the total is over -- I've never added it up.

BY MR. JESSEE:

Q. Is it possible it's over $10 million?

MS. STOKES: Objection. Form.

THE WITNESS: Again, I have no ability to answer that question. I just don't have the answer.

BY MR. JESSEE:

Q. Would your -- is that something your wife keeps up with, as far as the billing invoices and the tax returns, or is that --

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MS. STOKES: Objection. Form.

THE WITNESS: I don't think anyone has ever added it up on that kind of way over a decade. You know, this is going back over a decade.

It's certainly in the millions of dollars, but I can't tell you what the total would be from every case.

BY MR. JESSEE:

Q. Do you -- can you tell me how much you made testifying as an expert for plaintiffs in 2019?

MS. STOKES: Objection. Form.

THE WITNESS: No. I can't tell you that. I can tell you -- no. I mean, I don't have a total -- no idea what the total was.

BY MR. JESSEE:

Q. Do you agree it's over a million dollars?

MS. STOKES: Objection. Form.

THE WITNESS: Yes. Now, some of that is a little skewed, because opioids was --

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it gets a little -- it depends. Opioids was work over five years, for example.

So I didn't submit a bill until the end. So it was work over five years. And how do you -- your question -- do you mean in 2019? Sometimes -- I mean, you understand the answer.

BY MR. JESSEE:

Q. Right. As far as actually invoicing and getting paid though, it would have been over -- at some point, over a million dollars last year?

MS. STOKES: Objection. Form.

THE WITNESS: If you include the -- certainly, if you include the work for the prior five years, because, I mean, the cash -- the receipt -- I'm not even sure.

I assume I was paid in 2019, but that was -- I got paid in 2019 for work going back to 20 -- don't hold me exactly -- to 2015. So that's why it's not -- I mean, I can't just do it precisely by the year.

BY MR. JESSEE:

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Q. Do you have any other depositions or trial testimony scheduled currently?
A. There is a case -- there is one other case that may happen that I'm not sure I have been -- I'm not sure I can talk about. There is one other that comes to mind.
Q. And -- that's fair.
Other than the one you are not sure whether you can talk about, are you planning -- do you have any plans to testify at any trials coming up or --
MS. STOKES: Objection. Form.
THE WITNESS: I don't -- I don't get to make those decisions. I get called. So, I mean, the answer is, will I get called in New York state opioids? I don't know. I have done the deposition.
I think the MDL opioids has probably CT1. I mean, probably nothing else this year, I mean, on the manufacturers.
Essure -- again, let me just not talk.

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MS. STOKES: Yeah.
THE WITNESS: I'm a little uncomfortable.
MS. STOKES: You can ask about what's scheduled, but beyond that, this is improper.
MR. JESSEE: That is what I asked.
THE WITNESS: And I don't know what has been disclosed and what witness list or whatever, but, again, you have a pretty good sense of the cases I'm involved in. And you can probably -- you can -- what I would suggest is, just look at the cases I'm involved in.
And if there is trials, you can guess whether -- are they going to be trialed and I'm going to get called? And you know as much as I do, but there is one I just don't want to talk about.
BY MR. JESSEE:
Q. That's fine.
Have you been disclosed as an expert in any hernia mesh cases besides the ones we here for today?
A. I hope not.
Q. So not to your knowledge?
A. Yeah. There is always -- I say that. You understand. Sometimes you end up getting disclosed and you don't realize you are disclosed, but I should not be.
Q. You understand there's hernia mesh litigation against other manufacturers besides Bard?
MS. STOKES: Objection. Form.
THE WITNESS: Yes. I think I have seen that. I have not focused on it, and I have not been involved.
BY MR. JESSEE:
Q. You haven't reviewed the other products information?
MS. STOKES: Objection. Form. Vague.
THE WITNESS: You used the word hernia mesh. So I certainly have, for example, on Gore-Tex, on dual mesh. For example, I

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have -- because of looking at the 510(k) for -- in this case, the Gore-Tex is included in that 510(k), as we talked earlier.
So I have reviewed some of that stuff, because, obviously, it's in the predicate chain, but the answer is only as it relates to this matter.
BY MR. JESSEE:
Q. Anything -- as far as other products, would it be fair to say your review is consistent --
THE WITNESS: Is this mine?
MS. STOKES: Yes.
THE WITNESS: Thank you. I'm sorry.
BY MR. JESSEE:
Q. I will start over there.
With respect -- to the extent you reviewed other products, would it have been in connection with the regulatory submissions for the products at issue in this litigation?
MS. STOKES: Objection. Form.
THE WITNESS: Correct. And we are

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staying with hernia mesh, because, obviously, the California case that I testified on was vaginal mesh. I just want to be fair.

BY MR. JESSEE:

Q. And to be fair, you're not -- are any of the opinions that you offer -- or any of the review and documents you reviewed as part of that litigation, are you using any of that here in this litigation?

MS. STOKES: Objection. Form. Vague.

THE WITNESS: So there may be, again, general statements about FDA review process, right? I mean -- so not about specific matters, not about the specific devices, but the 510(k) process, substantial equivalence.

I am sure I would -- if you asked me questions, I would hopefully testify the way I would testify there, not on product specific matters, but on the regulatory framework, I would testify.

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And I'm sure we could find statements in this report that might match that report, again, on the general statutory regulatory framework.

BY MR. JESSEE:

Q. Sure. I understand that.

And as far as product specific -- any product specific opinions from that litigation not relevant to this litigation?

MS. STOKES: Objection. Form.

THE WITNESS: Different manufacturer, different set of very specific questions.

Again, I was testifying for the AG, I think, on just very specific questions.

MR. JESSEE: Doctor, I think now would be a good time to take a short break.

And we can talk about if we want to try to do a quick lunch now or move on. I'm fine either way.

MS. AMINOLROAYA: If you want, we can set up lunch. It's here.

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MR. JESSEE: Oh, yeah. That would be great. Why don't we go off the record.

THE VIDEOGRAPHER: We are going off the record. This is the end of Media Unit 2. The time is 11:57.

(A short recess was taken.)

THE VIDEOGRAPHER: We are going back on the record. This is the start of Media Unit No. 3. The time is 12:38.

BY MR. JESSEE:

Q. Dr. Kessler, I want to ask you a few questions about the supplemental -- or the errata sheet that was served on us yesterday. And this is going to be Exhibit No. 4. And I believe there's actually a copy of it, sir, right there for you to take a look at.

Is this a document that you put together?

A. It was -- it was under my direction answered review.

Q. Okay. And what was the purpose of this document?

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A. As you can see, I mean almost everything here is -- is just to make sure the report is accurate.

Q. Okay. Was there just, when you were reviewing the report in preparation for the deposition, little things you noticed that needed to be corrected?

A. Yes and no. Yes, I mean I did notice some things that needed to be corrected. But when -- sometimes I had the document pulled and underlined that it's not exactly in the right same cite. So this was a lot of just cite checking and typographical kind of stuff.

Q. And would it be fair to say that none of the issues that are addressed in this errata sheet are a change in any substantive opinions?

A. I think that's -- I think that's absolutely fair. They're just -- they're mistakes.

Q. Okay.

A. They're just typographical mistakes.

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I have one correct -- not a correction but one thing I promised earlier this morning that I just need to respond to, if can I --
Q. Sure.
A. Can I respond?
You asked me, and I said I think -- I don't know whether you said during your lunch. But you asked me, and I didn't have it in my head the different materials that went into the different devices, right? And I was looking. And I didn't want to spend more time. And I asked counsel.
And apparently there's a nice chart that's produced in the interrogatories of which materials are in which devices. So -- you can see that some of those devices -- you asked me specific about Marlex and Ventralight.
And certain of these devices had different materials at different times. And obviously I couldn't keep all of that in my head. So that -- that should be a fair record

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of what materials was used when.
Q. Okay. And is this the materials that you reviewed when you were preparing your report?
MR. JESSEE: And what I'm going to do, just so it's clear, I'll go ahead and mark this as exhibit --
MS. STOKES: It's going to be 20, I think.
(Deposition Exhibit 20 was marked for identification.)
BY MR. JESSEE:
Q. This is 20.
And this is something that is provided to you during lunch?
A. At my request.
Q. Yeah?
A. To answer your question.
Q. Okay.
A. I -- I -- correct.
Q. Do you know if you received that at any point earlier before lunch today?

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A. I don't recall seeing it, sir.
Q. The report your -- itself -- we were just talking about the errata sheet.
Was it a similar thing with the report itself where someone else actually typed it up under your direction?
A. Dictated it. Dictation is probably the right -- the right way to say it.
Q. Okay. And who was it that typed it when you dictated it?
MS. STOKES: I'm going to -- I'm going to object and instruct him not to answer that.
MR. JESSEE: Okay.
THE WITNESS: I'm -- I've been -- I have an instruction, right? I'm not going to --
BY MR. JESSEE:
Q. And you -- you've certainly answered that question before in your prior testimony.
A. Yeah. I mean I -- I -- I mean there -- there -- there may be -- I -- so it's

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counsel.
There may be a different person in the room at a different point in time. And somebody may get tired. But I tend to dictate. I may have typed a little, but I tend to dictate.
Q. The -- and do you know how many expert reports you've authored over the course of your litigation career?
A. I have --
MS. STOKES: Objection. Form.
THE WITNESS: I think you can -- I mean I tend to be pretty strict if I'm going to testify. Even in the State of California, where there's not reports required, I tend to make myself do an expert report.
So I mean I don't -- I wouldn't say count up the times I've test -- that -- it's not true. I wouldn't -- I wouldn't want to state that every time there's an expert report.
But I -- I tend to over -- I tend to do an expert report even when one is not

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required, just because I don't think that's -- I think it's better for the -- the parties. And it's also better for me.

BY MR. JESSEE:

Q. And you tend to be very thorough when you're putting those expert reports together, correct?

MS. STOKES: Object to form.

THE WITNESS: So I -- I try. Okay? The problem is, as with anything, these are -- these are five devices, plus, right, over many years. A lot of material, issues upon issues.

And not everything -- I would not say every issue gets identified perfectly the first time. I mean things get narrowed; other issues come up, you know.

I mean there's only so much -- as you know. I mean I'm trying to get a book out. There's only so much time one has, right?

I mean one could spend thousands of hours on mesh. I spent some -- 233 or something like that doing this. You know, you

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do what you can do. I mean --

MR. JESSEE: Sure.

THE WITNESS: -- that's reasonable.

I -- I try to do a good faith effort. But as you see, I -- someone caught an issue that I had not caught. And so let's leave it at that.

BY MR. JESSEE:

Q. When were you initially retained in this litigation?

A. If you can take -- if you can change the word from -- take out the word "retained," I can answer your question.

Q. Okay. When were you initially contacted?

Is that a better --

A. Yeah. That -- that would be fair. Because I --

Q. Okay.

A. -- never know what the word "retained" means.

I think it was March of '19.

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Q. Who contacted you?

A. I believe it was a -- the lawyer at Levin Papantonio, Matt Schultz.

Q. Would you agree that in the -- we -- we can agree with regard to the -- not the exact number but that you've done a fair amount of expert reports over the course of your work -- litigation work?

MS. STOKES: Objection. Form.

THE WITNESS: Over the last ten years, that's -- that -- that's a -- it's a significant list.

BY MR. JESSEE:

Q. And you agree that it's important not to cherry-pick the information that you rely upon, correct?

MS. STOKES: Objection. Form.

THE WITNESS: I try very hard to make sure I understand all aspects of an issue.

BY MR. JESSEE:

Q. Okay. And that would be -- include information that might be contrary to an

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ultimate opinion that you reach; it's important to look at that information as well, right?

A. I --

MS. STOKES: Objection. Form.

THE WITNESS: Absolutely. Because I know you're going to ask me about it. And I would -- would much rather -- I mean I tend to -- I try hard -- as hard as I can to include as much as I can within the limits of, you know, time and -- and human ability.

BY MR. JESSEE:

Q. And you understand, from your time -- in time serving as an expert, too, and as your -- from your law school days perhaps as well, that the federal rules require in the report a complete statement of all the opinions a witness -- an expert witness will express, right?

MS. STOKES: Objection. Form.

THE WITNESS: You -- you could -- so I -- I -- we can pull Rule 26. What I certainly know, and what I'm happy to -- what I

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certainly understand is my goal in that report is to try to give you the four corners of my report and, to the best of my ability, recognizing that, you know, there are going to be questions you're going to ask me and things that are going to come up. And I'm going to be responsive to.
So I -- I try very hard to -- to do that.
BY MR. JESSEE:
Q. Did you -- was there ever an engagement letter that was sent to you?
A. No. I don't believe so.
Q. So it was just a verbal agreement eventually that -- at one -- some point in time that you would serve as an expert?
A. I'm not even sure --
MS. STOKES: Yeah.
THE WITNESS: I'm not --
MS. STOKES: I'm going to object and instruct him not to answer.
MR. JESSEE: As to whether they --

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when he became an expert?
MS. STOKES: That wasn't the question.
BY MR. JESSEE:
Q. Okay. So there's no --
MS. STOKES: If you want to ask a more --
BY MR. JESSEE:
Q. -- there's no engagement --
MS. STOKES: -- precise question.
BY MR. JESSEE:
Q. -- no engagement letter?
A. There's -- there -- there's -- there's no engagement letter.
Q. All right.
A. You know --
Q. You did agree to serve as an expert for plaintiffs' counsel at some point in time in this litigation?
A. I -- I think -- I think the day I signed the report. Look, exactly what point that is -- I mean, as always, there's a

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continuum.
I didn't know about this case when I got the first phone call. I didn't know what the issues were. I didn't know whether I would have anything helpful that I would be able to offer the court, right, to -- so I mean you learn that over time.
Q. Had you worked with counsel who contacted you before?
A. Counsel who contacted me, I had. I had not been his -- he -- the counsel who contacted me was just to make an introduction to me to somebody else who I had not work --
Q. And who was that that you were introduced to?
A. To Tim O'Brien.
Q. Okay.
A. I have no recollection of working with Tim prior.
Q. You ever designed a medical device?
A. Yes.
Q. Was that the syringe cap when you

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were -- back around when you were working in the Bronx?
A. You got it. Boy, you -- you really have --
Q. I've -- I've read the --
A. Either that, or you had a camera in my office in the Bronx when I was sitting there trying to -- to do this.
Q. Yeah. And did -- that never actually though went to market, right?
A. Yeah. I had -- I mean I've -- that was -- were -- my preFDA days I was medical director of a hospital trying to figure out how medical staff would not get stuck.
Q. Right. Exactly.
And that -- that never -- that -- you ever -- that -- did you file a patent for that device?
A. I may have got -- I don't think I went that far. I mean I think I may have done some steps. But I never went that far.
Q. Okay.

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A. I mean I think I hired somebody to do a patent search and --
Q. Okay.
A. -- et cetera. But I don't believe I...
Q. Other than that -- and that was -- would have been, what, the -- that's 1980s, 19 --
A. You have it. Beginning of the AIDS epidemiology.
Q. Other than that -- the cap for the syringe, have you ever designed a medical device?
A. So I -- so I have been part of discussions you know, that have sat there and talked about medical devices, certainly on boards, et cetera.
But I don't want to -- I don't sit there. And I -- I didn't drew -- draw the schematics. I don't want you to leave that impression. That's not my area.
Q. Have you ever tested a surgical

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mesh?
MS. STOKES: Objection. Form.
THE WITNESS: I've done no trials and studies of surgical mesh.
BY MR. JESSEE:
Q. Okay. And when -- just so we're clear, when we're talking about studies, that -- are we -- that would include -- you haven't done any like mechanical testing or anything like that of surgical mesh, correct?
A. I'm in the -- I'm a regulatory expert. I mean so -- so the record is clear, even FDA -- for the -- even FDA doesn't test medical devices, I mean with -- with a few exceptions.
Q. Sure.
And -- yeah.
And then I'm just trying to clarify then, you know, what areas -- and -- and I think you've been consistent.
You're talking about the regulatory set of things, not -- not going into the

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mechanical engineering side of things.
A. Correct.
MS. STOKES: Objection. Form.
THE WITNESS: Now -- now, to -- now there are mechanical engineering things that are part of the regulatory submissions. And I'm happy to go into it if it abuts that regulatory submission. But I would not be the one who would do that -- those tests.
I mean I've done animal testing, not of -- of -- in other contexts. And I'm imperfectly competent to discuss with you animal studies. But I didn't do any studying here. But I'm happy to discuss studies from a regulatory context and what they mean.
BY MR. JESSEE:
Q. The -- I see the -- and I didn't ask about this earlier. There is a PerFix Plug that is here on the table.
Did -- is that something you brought with you?
A. I -- I just have -- I have all the

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devices with me. They just happened to be -- I just was -- I was looking at one thing about it this morning.
Q. Okay. And those -- were those provided to you by counsel?
A. Yes. I asked for it. Yeah. I -- I don't think these are things I can go into the Walgreens and buy.
Q. No. I mean -- no.
I mean they're obviously prescription medical devices, right?
A. Yes. That -- that -- that's correct.
Q. And the --
A. I -- I just asked to have them.
Q. Any reason in particular the PerFix one -- PerFix Plug plug one is on the table?
A. Because I -- I wanted to see -- I wanted to feel something this morning about that device. And I -- I just -- I mean something popped in my head. It's one of those 5:00 a.m. questions I had. And I just wanted

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to check something.

Q. Did you have any experience with hernia mesh prior to your involvement in litigation?

MS. STOKES: Objection. Form.

THE WITNESS: Not -- not -- I had -- I had experience with some of the materials that have been used, for example, and tested as hernia meshes, et cetera, over time but not as these products are designed.

BY MR. JESSEE:

Q. What about ePTFE; is that a material you had experience with prior to your involvement in litigation?

A. I did not --

MS. STOKES: Objection.

Go ahead.

THE WITNESS: Sorry.

I did not have experience with ePTFE or PTFE before. It was not something that rose as an issue of when I was at FDA.

BY MR. JESSEE:

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Q. What about the separate technology -- do you know -- you know -- understand --

A. I -- I --

Q. -- what I refer to when I say --

A. I -- happy to discuss that the rest of the afternoon.

Q. Well, and we'll get there.

But I just want to know -- just my question now is did you have experience with that prior to your involvement with litigation?

A. Not -- not --

MS. STOKES: Objection. Form.

THE WITNESS: Not that specific technology. I don't remember it being -- coming up as an issue. And I don't remember the dual -- the dual mesh application rising to the commissioner.

BY MR. JESSEE:

Q. The -- I want to just briefly look at Appendix C to your expert report.

And in -- it's -- this is -- I

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believe you state in your report, the body of it, that this is a list of documents that were either provided to you or that you found independently?

A. That's a fair statement.

Q. Okay. And would it be accurate to say that not -- you don't rely on every single one of those documents for your opinions?

MS. STOKES: Objection. Form.

THE WITNESS: I -- I -- I think that's probably well stated. I specifically used the word "considered" rather than "relied." I think that -- I think that -- the answer probably to your question is yes, I know. I mean I...

BY MR. JESSEE:

Q. Okay. Did you review every one of the documents listed in Appendix C?

A. At -- at some point I probably touched, I mean, or scanned or -- I mean probably more -- let me put it more -- be more exact.

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I didn't -- I mean there are a lot of depositions, for example, here. There are a lot of articles. I would be on PubMed, or I would even ask on depositions. I would be searching multiple depositions for key words at different points in time.

So I think, again, some of this is the result of search -- or I would have searched for these things. I don't want to give you the impression -- there's no way that I could have read thoroughly every single one of these documents. But somehow they were searched or -- or re -- you understand what I'm saying.

Q. Yes, I do.

And so I'm focusing -- so to just sort of summarize this Appendix C, you have these Bates labeled corporate documents that were produced by Bard as part of it, right?

A. Correct.

Q. You have the literature as --

A. Correct.

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Q. -- as a section in here. You have depositions.
A. Correct.
Q. And then you have I think a general or sort of miscellaneous section at the end?
A. Just the FDA documents after the --
Q. Sure?
A. -- depositions, yes.
Q. So just with the -- have you -- just focusing on the corporate documents listed here, the Bates numbers one, have you reviewed all the documents that's -- are listed there?
A. I wouldn't want to --
MS. STOKES: Objection. Asked and answered.
THE WITNESS: I wouldn't want to swear to you that I've reviewed every single page of all those documents. I mean I am a -- I'm an avid searcher, right? I mean -- I mean I think as the lawyers -- I mean, if you asked the lawyers, no lawyer feeds me anything.
I mean I tend to search. I ask for

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the database, and I search documents. And the reason there's so many documents here is because, you know, you -- you get back -- you see a lot of things.
BY MR. JESSEE:
Q. Yeah.
Is it -- when -- when you access to the database, is through Relatively that you go in there and search?
A. The -- the answer to your --
MS. STOKES: Yeah.
THE WITNESS: The answer to your question is no. But I'm not going to go there. Because she's going to instruct me --
MS. STOKES: Yeah.
THE WITNESS: -- not to --
MR. JESSEE: Okay.
THE WITNESS: -- tell you the actual -- probably the name of the database.
BY MR. JESSEE:
Q. Oh, okay. That's fine. Are you physically searching it, doing the searching

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yourself?
A. Yes, sir.
Q. Is there a record of your search terms that you used?
A. Not that I am aware of. I -- I -- I don't keep any record.
Q. What -- what search terms did you use?
A. A lot.
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. Can you give an example of some of them?
A. Last night? So I can tell you last night I probably searched 160 --
MS. STOKES: I --
THE WITNESS: I'm sorry.
MS. STOKES: I'm just going to caution you that, to the extent that you were consulting with counsel on -- I'm going to instruct you not to answer.
So with that caution --

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THE WITNESS: I can tell you I was -- I searched 168 days. I could -- 180 -- 68 day implant, a hundred and -- I mean there were -- that -- I mean just that -- that's one that -- I mean probably every version of that I was searching last night.
BY MR. JESSEE:
Q. Why were you searching for 168 days?
A. I had found a document that was -- it was an animal study. I had found a document. There was a partial document. I could never find the full report. And I was trying to understand the actual animal data at 168 days.
Q. Did you ever find it?
A. I found a table, yeah.
Q. Did you ever find the full report?
A. No.
Q. The "Published Literature" section of your appendix --
A. Yeah.
Q. -- were these -- is this a mix of

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documents that was provided to you and that was -- you found on your own?

A. That's a -- probably a fair statement. This is -- I tend to be cumulative, right?

This is not of -- there are a lot of documents here. And I'm willing to -- you know, so I do a lot of PubMed searching myself over time. But I tend to ask for documents also.

So this is -- this is not meant to be any -- don't read anything -- I just tend to be cumulative.

Q. And -- and you seem to be very thorough.

And I'm -- given the volume of literature here, I take it you didn't read every single page of every one of the articles?

MS. STOKES: Objection. Form.

THE WITNESS: That's a fair -- you can be certain I searched that, right? So I'm -- I'm -- at a certain point in time, I'm

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looking at certain questions, you know, over a period of months. And so I am searching that stuff.

BY MR. JESSEE:

Q. If you --

A. And I'm not saying anyone has -- you know, are -- they're relevant or even -- not that I'm relying on them. But -- but somehow I've touched them. I've touched upon or researched the documents that -- those words or including those words.

Q. Did you try to find all of the studies related to the Ventralight?

MS. STOKES: Objection. Form.

THE WITNESS: I try to be comprehensive. I would never -- all the studies? Say that again.

BY MR. JESSEE:

Q. Did you try to find all of the studies on -- and we are talking about the clinical literature -- the published literature here just -- let me -- I'll rephrase it.

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With regard to the published literature, did you try to find all the published literature on the Ventralight?

MS. STOKES: Objection. Form. Assumes facts.

THE WITNESS: No. I was compulsive and tried to find all the studies that -- and you can see from my -- I tried to find all the studies that Bard had done on Ventralight.

I tried to -- I tried to be comprehensive. So, I mean, I was obsessive about trying to find every one of Bard's studies.

Do you understand?

BY MR. JESSEE:

Q. Uh-huh.

A. And that takes a lot of time, right, because there are studies done over time. So that, I can tell you, I worked very hard to try to assure and probably accomplish that.

I tried to be comprehensive in searching for Ventralight studies in clinical

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stuff, but I don't want to represent that I have every study.

I did -- on the question that I opine on -- one of the questions I opine on on reabsorption, I tried to include all the studies that I -- with regard to ST, the length of reabsorption, the complete healing period.

So there, I tried to be more focused, but I don't want to state that I did every study.

Q. What about -- the same question for the Ventralex, in that with regard -- would it be the same for the Ventralex, in that you made a comprehensive search of Bard's studies, but not the medical literature in general about Ventralex?

MS. STOKES: Objection. Form.

THE WITNESS: So there there were two aspects of my report on -- or several aspects. Just as I may have focused more -- I was very compulsive on making sure I had the Ventralex studies by Bard.

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With regard to what was in the medical literature, I worked -- I focused a little more and was a little more comprehensive when it came to Ventralex and, for example, infection rate.

So there was a little more focus there than on other aspects of Ventralex in the clinical literature, but I was -- I mean, I was as compulsive as I think anybody could be on having all the studies of Bard.

BY MR. JESSEE:

Q. What was the infection rates that you saw for the Ventralex in the literature you reviewed?

MS. STOKES: Objection. Form.

THE WITNESS: The answer is, which study?

BY MR. JESSEE:

Q. Well, in the overall. Can you summarize what the overall infection rate for Ventralex was?

A. I can give you that. Can I just get

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my Ventralex infection papers?

It depends on which study we are dealing with, and I can give you --

Q. This is Exhibit 14?

A. Yeah. You are ahead of me, right? So you can see here --

Q. It looks like, Doctor, that you have several pages of different studies -- or several studies pasted on this?

A. Yeah. So, again -- so you can -- if you want the answer to your question, each one -- we can spend 20 minutes on each one of these studies, and they all had different numbers in here.

And I tried to -- I think, on the infection rate, I tried to include, you know -- PP meshes show infection rates ranging from 2.0 to 4.2 percent, you know. Citation is omitted.

In contrast, ePTFE show more or wide ranging infection rates ranging from 0 to 9.2 percent when open surgical approach is used -- again, citation is omitted -- and only 0.0 to 1

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percent when a laparoscopic approach.

So there are multiple different rates. There is a substantial infection rate, 8 percent in this series, particularly with MRSA.

So the answer to your question, it depends on which study.

Q. In those two studies you're looking at right there, those aren't specifically on Ventralex, correct?

A. They are on ePTF. So let's just -- this is not, but these are on ePTFE. And I would have to go back and -- we'd have to pull each one of these citations. And I have each one of these studies in a notebook.

Q. What I am wondering is -- because I didn't see in your report about a discussion of the infection rates published for Ventralex and studies looking at the Ventralex specifically.

MS. STOKES: Objection. Form.

BY MR. JESSEE:

Q. Is that -- and correct me if I am

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wrong. Was that -- do you have any specific clinical studies in there, studying the Ventralex, a discussion in your report?

A. I would have to go back. Let me go back and check that specifically. I have a list of all the studies. I don't have it in my head, but, I mean, I am willing to -- whatever the studies show the studies show.

Q. Okay. I mean, have you done a comparison of the -- what the infection rate for Ventralex is compared to other ePTFE products?

MS. STOKES: Objection. Form. Vague.

THE WITNESS: Yeah. So I choose my words very carefully in the report. Let me just -- let me just go to the infection.

I am not aware of Bard doing any -- and this is one of the issues that I have. I think what the opinion is -- I have no -- I'm not aware of Bard doing any infection, antimicrobial sensitivity of microbes getting

stuck, whatever the kind of -- the different kind of tests to see whether material harbors and infection stays collected in Ventralex. I don't see those studies.

My opinion is, there certainly was a recognition, because ePTFE was submicronic. And there was an issue of clearance and a general acceptance within Bard about a higher infection rate with ePTFE that my issue is the lack of doing the design control to determine what -- I mean, to minimize the infection rate and, if, in fact, it was higher, to warn.

So I think I am very -- I am very careful in how I state my opinion, if my memory serves me right.

BY MR. JESSEE:

Q. And I think you are right. I'm just looking at the summary, where you say: "To the extent that Bard had evidence of higher infection associated."

I'm looking at the summary of Section No. 9 in your report.

A. Yes. If I can get there. Just give me what page.

Q. And I'm actually looking at the -- it is on Page 90. I was just looking at the table of contents too.

A. Just give me one second. What page, sir?

Q. 90?

A. Page 90. What paragraph?

Q. Section 9, 262 and 263.

A. Right. But there's also -- if you look at -- infection begins a number of pages earlier.

Q. It does. I know. I am asking though specifically about the language you choose to use here, saying, "To the extent that Bard had evidence."

You are not saying that -- you are not going to offer an opinion that -- what the infection rate in nonBard clinical literature on the Ventralex is, right?

MS. STOKES: Objection. Form.

Vague. Misstates.

THE WITNESS: I'm sorry. Just help me understand. NonBard --

BY MR. JESSEE:

Q. Medical literature, medical --

A. NonePTFE devices?

Q. No. I will ask a better one.

It sounds to me from what you are saying, if I can summarize it, your focus has been on the testing or lack of testing, in your view, that Bard did on these products; is that fair?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. I think that's a significant part, yes.

BY MR. JESSEE:

Q. And with regard to though the -- there is obviously -- there is for these products -- like the Ventralex has been on the market for a long time, correct?

MS. STOKES: Objection. Form.

THE WITNESS: Depending on what --

we can have an exact date, '08 Ventralex, depending on which one we are talking about, PET was '01.

BY MR. JESSEE:

Q. Right. And there has been -- in clinical and peer reviewed medical literature, there has been studies involving the Ventralex over that time period, right?

MS. STOKES: Objection. Form.

THE WITNESS: We have -- we have certain data on ePTFE. I am not sure I have seen any Bard studies on infection rate.

BY MR. JESSEE:

Q. I'm not talking about Bard studies. I am talking about studies in peer-reviewed medical journals, not that Bard did, but the physicians using the advice data they published on the Ventralex, are you aware of those studies?

MS. STOKES: Objection. Form. Assumes facts.

Go ahead.

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THE WITNESS: So, again, I am aware of general ranges of infection rates of ePTFE implanted. We can go -- we talked earlier.

If you have a specific Ventralex infection rate in the literature that is only Ventralex infection rate, I would be happy to see it.

I have -- the studies I have seen here -- let's just go back -- in the report are on ePTFE implants and I don't believe are just Ventralex.

Hold on one second. Give me one second.

I don't have readily at my fingertips the kind of study that you are talking about that just has Ventralex ePTFE. I certainly don't have it in the Bard record.

BY MR. JESSEE:

Q. You have also looked at lit -- some of this literature that you have isn't just all stuff you found through Bard's files, right?

A. That's correct, but I do that, not

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to get to a legal term, but that's sort of -- if you look at Badhwar's testimony, if you look at Ciavarella even, I mean, they recognize there was a higher infection rate in their depositions.

And with that and with the general numbers of -- in those studies, the company was on notice that there were certainly issues of higher infection rate.

And I said, Look, with that being known out there by your own statements and your own testimony and the general literature, there was an obligation to be able to design -- to have adequate design controls to test whether, in fact, there was a higher level of infection and to minimize that.

That's where my report is, but others can talk about what the exact infection rate, but I think the record shows the company was on notice that there was a concern about that.

Q. Switching a little bit back to the

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line of questions I had, we have been talking about -- just briefly about Ventralight and Ventralex.

Would it be true for PerFix Plug and 3DMax as well, that your focus was more on the Bard documents and case studies on those devices as opposed to the medical literature overall looking at those devices?

MS. STOKES: Objection. Form.

THE WITNESS: No. In that -- I think that's a little different, if I may. The issue there was, again, PerFix Plug, more material, more -- a different -- I mean, the type of design.

I mean, there was more mesh, but I certainly -- there, the issue and, I think, the opinion among others is the failure to warn on chronic pain.

And I do believe I cite studies -- happy to pull them for you -- in the medical literature, where chronic pain -- not only the complaints, not only in the company's own

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documents -- and I don't think there's any -- it was in the European label, I think.

It was in the European clinical evaluation that there was chronic pain associated with that device and, certainly, a recognized adverse event and wasn't on the label.

So I certainly -- I cite studies just to show that chronic pain was well established and should have been in the label.

BY MR. JESSEE:

Q. So that's a little different than the Ventralex and Ventralight that we were talking about?

A. Exactly. You got it. So there is a little more emphasis.

Q. Did you review the FDA review memorandum for any of these 510(k)s?

A. Yes. When they're available. Many of them were FOI'd, but you have to be specific. I have tried to look at the FDA file when it exists. It doesn't always exist.

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Q. Did you review any documents on the physician training programs that Bard provided for hernia mesh surgeons?
MS. STOKES: Objection. Form.
THE WITNESS: Yeah, yes. At certain points, I was looking -- I forget the exact context, but I was looking for slides that were used in training programs and found some. So I was focused on training at some point. I looked at some of those decks, I believe.
BY MR. JESSEE:
Q. That didn't make it into your report though, right?
A. That's correct, but just so -- for the record, I do remember searching -- I can't tell you exactly how my thought processes went, but something took me to understanding about -- wanting to know that. So I did search.
Q. The schedules that are attached to your report, there are six of them. I'm not going to go through -- yep. Six of them.
I'm not going to go through them in

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detail this moment, but are these documents that were created under your direction, or were they provided to you?
A. No. These were done under my direction and review, but they were not done by me. They are tend -- they are tended to be objective facts.
If we want to talk about -- for example, you asked me a date, right? What date?
And I just wanted to have those things available so that I could refer to it today or you and I could refer to it today, but if there is any mistake in the -- they were under my direction and review, but if there is any mistake in there, I am happy to correct it. It was just trying to get the core -- my head around basic things about these devices. So --
Q. Okay.
A. -- I mean, it's changes in the IFU, some sense of the chronology of what happened when.

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So those were specifically done at my request, and I looked at them, but they are not meant to be -- there is no buried opinions in them.
Q. And I guess I am just trying to make sure I understand. So, for example, the changes in the IFU, did you ask, Can I see a chronology, showing the different changes over time, or did you walk through and say, Hey, this is what this one says. This is what you asked for?
A. I admit there wasn't time. I mean I may have done a little of the second, but it was more of, Can we just -- I need to make sure that I have a document that shows what the label said at different points in time for this device. So it was a very specific instruction.
Q. Okay. So the same thing. When we are talking about Schedule 1, the device history schedule, is that where you -- something where you asked for a basic sort of chronology of this?

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A. Of the different Bard devices and -- but I asked to make sure that they didn't -- that they were just quotes from the device -- from documents and just give us some sense of when different things were, but I recognize, you know, a full chronology of every interaction with FDA would take, you know, boxes and boxes. So that is not -- that just gives us some, you know --
Q. So it's the same basic idea then for the device schedule, the decision tree. You asked for these particular things, and they provided you with --
A. The predicate -- the predicate things, yeah. To the best -- and then I tried to play some role in there, but, again, what it does is, you just have to go through each application, you know, and pull the predicate and then pull the predicates of the predicate of that other application.
So it's -- I mean, it's a pretty regimented kind of operation, but I did not do

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that myself. I did review it.
Q. Let's talk some about the FDA regulation of medical devices.
A. Happy to do that.
Q. I know you know a thing or two about that.
In the U.S., obviously, the FDA is the agency that's -- who regulates medical devices, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Yeah. I don't think that's a trick question.
BY MR. JESSEE:
Q. I was hoping this would be noncontroversial.
A. I'm going, Well, is there any National Bureau of Standards? Is there anything else that -- yeah. I think that's a fair standard -- a fair question.
Q. Would you agree that the FDA is charged with the responsibility for protecting the public health by assuring the safety,

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efficacy, and security of human and veterinary drugs, biological products, and medical devices?
MS. STOKES: Objection. Form.
THE WITNESS: Yeah. You are quoting me again on some FDA document, and that's fine.
Yeah. That's general. Let's just see.
You said safety and -- can you just -- this is rough. What was --
BY MR. JESSEE:
Q. Safety and efficacy and security of --
MS. STOKES: Same objection.
THE WITNESS: Yeah. So that's -- the answer is, it's complicated.
BY MR. JESSEE:
Q. Okay. Can you -- you don't agree with that, that they are charged under the law with that responsibility?
MS. STOKES: Objection. Form.
THE WITNESS: The law is much more

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specific. You can't make that general statement, based on the statute.
You know, I'm sure we will spend the next 40 minutes discussing whether substantial equivalence is safety and effectiveness.
BY MR. JESSEE:
Q. Are you putting a time limit on me here?
A. I'm happy to do as much as you'd like. I'm happy to do as much as you'd like.
So the question is, is substantial equivalence -- you can pick certain -- does it go to safety and effectiveness? Is it substantial equivalence? So you got to be careful. I'm not answering that.
Q. I'll tell you. That language I just read is straight from the FDA web site.
A. But be careful. You know, the FDA web site is -- some of that is apple pie and motherhood and all things good and PR stuff.
I mean, I think if you want to know what FDA is charged with, you have to look at

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the statute and the regulatory history.
And as you know well, you know, over your career, there are devices where you have to affirmatively show safety and effectiveness from premarket approval.
And the 510(k) process is based on substantial equivalence, which has touches of safety and effectiveness, but it's not the same kind of review. So that's where the rub is.
Q. And I promise you. I'm going to let you -- we're going to get into that part of it first. And I just wanted to sort of start from a little bit higher level here though.
With regard to the FDA's oversight of medical devices specifically, one aspect of it -- and we will talk about -- is the premarket review of devices, correct?
A. Yes, sir.
Q. Another aspect of it would be post-market surveillance involving devices, correct?
A. Correct. Sure.

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Q. There is other aspects of the FDA's regulation of medical devices that involve the entire lifecycle of a product, right?
MS. STOKES: Objection. Form.
THE WITNESS: I'm not sure -- I understand -- I understand clearance review, post-market surveillance.
BY MR. JESSEE:
Q. For example, quality system regulations you are talking about.
A. Sure. Well said, sir. That is correct.
Q. I am tempted to stop now with that compliment, but I think we will keep going.
A. No. You have that exactly right. I mean, I think that is well said. I just wanted to understand --
Q. That's what I was getting at.
A. -- what you were referring to in the lifecycle.
Q. And that would include then, as part of that, inspections that FDA will do?

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MS. STOKES: Objection. Form.
THE WITNESS: It's all the 820 -- we wrote the regs. What did we write? The final regs were '96, I think, that we wrote. So it's all those aspects of the QSM and QSRs.
BY MR. JESSEE:
Q. So the -- and this is, I think, mostly in your report. I just want to make sure we are sort of walking through the time line of the regulations.
We obviously have, in 1976, the medical device amendments that set forth the three classes of devices?
MS. STOKES: Objection. Form. Is that a question?
THE WITNESS: I mean, there was a number of different ways of slicing that world.
BY MR. JESSEE:
Q. Okay. Maybe -- that probably wasn't a good question. Let's look at your report. Maybe it's easier.
Paragraph 14.

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A. Thanks.
Q. You say here that the FDA classifies devices according to a level of regulatory control necessary to provide a reasonable assurance of safety and efficacy?
A. Page 14?
Q. No. I'm sorry. Paragraph 14.
A. I apologize.
Q. That's all right. Let me make sure I have it, yeah. Actually, I guess you said -- let's make sure I read it correctly.
It says, "Congress established" three levels -- "three classes of devices, based on the regulatory requirements needed to provide" a -- to provide "reasonable assurance of their safety and effectiveness"?
A. Correct.
Q. And with Class III being the highest risk, Class I being the lowest?
A. Correct.
Q. And it's the FDA then who determines which class a device or a category devices will

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be classified in, right?
MS. STOKES: Objection. Form.
THE WITNESS: There were panels going back to the '70s and '80s, but in the end, you are correct.
BY MR. JESSEE:
Q. Okay. In the process for classifying a -- for determining what classification a device will be in, there is sort of different steps. And I think you laid this out in the report.
The first step is that the FDA will receive a recommendation from a device classification panel, right?
A. In some instances, yes. That was the way it was done initially.
Q. And those device classification panels, those were, basically, advisory committees?
A. Fair. Actually, some were intergovernmental, if my memory serves me right.

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Q. And those will often be experts and those the type of devices that are being classified?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. There was expertise, but some of these were not -- they weren't the quite device panels as you have today of the advisory committees. They were certain groups that FDA put together, if my memory serves me right.

BY MR. JESSEE:

Q. They would certainly include physicians who were using those types of devices though, right?

MS. STOKES: Objection. Form. Assumes facts.

THE WITNESS: Be careful. I mean, you're testing my memory. I am not sure exact -- some of those device panels were a little strange.

BY MR. JESSEE:

Q. We will look at the Federal Register

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for this hernia mesh in a second. I am just trying to get an overall view first.

A. Sure.

Q. The next sort of step after the FDA receives its recommendation from the advisory committee is that they publish the panel's recommendation for comment along with a proposed regulation classifying the device?

A. Sure.

Q. And that can sometimes take several years?

MS. STOKES: Objection. Form.

THE WITNESS: Absolutely.

BY MR. JESSEE:

Q. The --

A. Take preemptive devices, you can probably substitute the word decades.

Q. And after that time, where they're for public comment, eventually, the FDA will publish the final regulation classifying the device?

A. Hopefully.

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Q. Ideally?

A. Ideally. Again, sometimes after decades and -- but, I mean, you have to understand. There were a lot of devices on the market beforehand.

And congress says, Oh, divide the world up into classes. And all new device -- you know, it's just not as simple, because you have all these grandfathered devices.

And then you have a device that comes on the market the day after that grandfathered device and is it different and -- I mean, it was a very complex and, in some ways, cumbersome system.

Q. You would agree that the vast majority of devices classified as Class II are then subject to the 510(k) pathway?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. I mean, that's the way it turned out. It's not the way congress originally wrote it.

BY MR. JESSEE:

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Q. In 1976?

A. Yeah. All implants were supposed to be Class III. So it sort of -- you know, everything sort of moved over time, I mean.

Q. And you know that there were implants that were going through the 510(k) process while you were commissioner, right?

MS. STOKES: Objection. Form.

THE WITNESS: Well, congress changed that standard in 1990, right? And there were implants that I lived that hadn't -- you know, the problem was the breast implants. They were never tested.

They were premium Class III, and they had never even gotten reviewed. So this was a process that took decades.

BY MR. JESSEE:

Q. And when you were talking about in 1990, that would be the Safe Medical Devices Act or SMDA?

A. Right. To which we wrote the regulations.

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Q. Right. And that was something that was passed and went into effect when you were commissioner, or was it before?
A. I think it was right before, but I think we did some of the 820, and those other things were in response to the SMDA.
Q. And the SMDA was certainly important legislation for the FDA's regulation of medical devices, right?
MS. STOKES: Objection. Form.
THE WITNESS: The correct answer would be, any legislation that congress passes is important legislation, right?
BY MR. JESSEE:
Q. Well, the SMDA in particular though, it changed -- it changed several aspects of the FDA's regulation of medical devices, like the example you just gave, right?
MS. STOKES: Objection. Form.
THE WITNESS: Sure. I mean, it -- what was originally started -- both the implants as well as substantial equivalence was

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further defined in the act.
BY MR. JESSEE:
Q. And then in the SMDA, it required the FDA to review pre-amendment devices and either down classify them or require them to go through the PMA process, correct?
MS. STOKES: Objection. Form.
THE WITNESS: I've lived that, yes. And that's a mess.
BY MR. JESSEE:
Q. That's something you did with the breast implants, right?
A. Exactly. And that took decades. And that's still -- I think it's just about to be cleaned up today.
Q. In the SMDA, it also defined what the standard for substantial equivalence is, right?
MS. STOKES: Objection. Form.
THE WITNESS: You'd have to pull -- I think you are right. I think there is language -- do you have the actual language of

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the SMDA?
BY MR. JESSEE:
Q. I can tell you also that it's -- I'll tell you what. We will pull it for you.
Do you have any reason to doubt that?
MS. STOKES: Objection.
THE WITNESS: Whatever the statute says, the statute says. I will agree. I'm not, you know -- I mean, I just don't have -- I mean, I don't remember exactly what was in those amendments.
BY MR. JESSEE:
Q. And there were also though in the amendments -- I don't know if you remember. If you don't -- provisions relating to improved post-market surveillance of devices?
MS. STOKES: Objection. Form.
THE WITNESS: There was a shift to -- Class II devices was supposed to have performance standards in the '76 act.
BY MR. JESSEE:

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Q. Right. And then --
A. And the problem was, they got around to 1990, and none of Class II had -- there was maybe one or two performance standards, and that was it.
So we went, Holy, how are we going to -- we are saying all these Class II are on the market because there is performance standards, but there is no performance standards.
So they changed the terminology to special controls, right, and said, Well, FDA -- they had to give the sense to the American public that, Well, there is some level of protection to these devices that are -- come through the 510(k) process, and said, Well, there can be special controls. And they include a range of different tools, right?
BY MR. JESSEE:
Q. Would you agree that the SMDA authorized the FDA to require manufacturers to perform post-market surveillance on permanently

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implanted devices if --
MS. STOKES: Objection. Form.
THE WITNESS: There were -- different tools were given to FDA at different points in time.
BY MR. JESSEE:
Q. And one of the things SMDA authorized was the device recalls and civil penalties for violations of the FDCA?
A. That, I remember, yes.
Q. And in your experience at the FDA, if the FDA determines that a device poses a safety risk, does it have the regulatory tools needed to attempt to address that risk?
MS. STOKES: Objection. Form. Improper hypothetical.
Go ahead.
THE WITNESS: Not as much as you would think. I mean, once a device is on the market, you know, FDA -- the burden falls on FDA.
And, you know, I dealt with one --

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you know, just the breast implants took me four or five years of enormous back and forth. And there is a lot of litigation.
So it's -- FDA -- it's not that FDA can snap its fingers and say, The device is off the market. No problem.
BY MR. JESSEE:
Q. But there are enforcement actions that the FDA can take if it has concerns about the safety of the device, right?
MS. STOKES: Objection. Form.
THE WITNESS: Not -- I wouldn't agree to the way you phrased it.
BY MR. JESSEE:
Q. Would you agree that if the FDA is concerned about the safety or efficacy of a device, it can demand a recall of the device?
MS. STOKES: Objection. Form.
THE WITNESS: I have to go back and read the legal standard. Most of the recalls are -- I mean, I have to read the -- if you give me the statutory standard on recall.

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I just want to be careful on what has to be shown under the recall standard, what FTCA has to show. FDA can't -- FDA has to meet certain standards once a device is on the market in order to recall. Most recalls are voluntary.
BY MR. JESSEE:
Q. Do you agree the FDA can ban devices under certain circumstances?
MS. STOKES: Objection. Form.
THE WITNESS: It depends -- again it depends on the -- it has to meet certain standards.
BY MR. JESSEE:
Q. And do you agree that the FDA can impose restrictions on the sale or distribution of a device?
A. It depends on -- you'd have to get the exact standard. It just can't snap its fingers and do those things.
Q. I am not saying that. And, obviously, there's -- but it's one of the

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options that the FDA may have to address a safety problem, right?
MS. STOKES: Objection. Form.
THE WITNESS: It may have -- again, we'd have to -- you have to give me the statute so we can be exact on --
BY MR. JESSEE:
Q. So that one is in the Section 518A of the FDCA.
A. You give me -- is it in my report? I mean, I just -- I'm happy to pull it up. Whatever the statutory standard is, if you pull up that language, I'm happy to agree with you that the statute says what the statute says and sets out the standard.
I am just saying that I had problems -- concerns about the safety of devices, and it's just not as simple -- does FDA go ban it, does FDA just recall it? The device has been used; it's in people.
It's very hard to recall a device that is in people, right? I mean, it's very

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hard to ban a device that is in people, right?
So that's -- those are the realities, because if you ban a device and it's been implanted, you know -- I mean, I've had people cut out devices out of their body. So you got to be very careful here.
Q. Now, the FDA has the power to require manufacturers to notify all healthcare professionals who prescribe a device of its health risks.
Do you agree with that?
MS. STOKES: Objection. Form.
THE WITNESS: It depends. Again, whatever your list comes from the statute, I am happy to agree to the --
BY MR. JESSEE:
Q. That those are the powers the FDA has?
A. Those are the powers. You are reading portions of the statute and lists, but, again, there is a standard that applies to each one of those. I just want to be careful.

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Q. The FDA can issue public health notifications for a device, right?
A. Yes. Again, within certain process constraints.
Q. And there is legal actions that can be taken in connection with the Department of Justice, such as seizures, injunctions, prosecution, civil monetary penalties?
MS. STOKES: Objection. Form.
THE WITNESS: If certain standards and certain things are met. Each one of those requires enormous resources. And, you know, each one takes an enormous about of energy.
And, of course, there is a great -- I mean, each one consumes a great deal of energy from the agency. And there is a limit, because of resources, to what the agency can do and how many of these things it can actually implement.
BY MR. JESSEE:
Q. In one of your speeches that you gave, the Hastings speech, when you -- I forget

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the time period, but you stated that when you assume the position of FDA commissioner, one of your top priorities was more vigorous enforcement of the law.
Is that an accurate statement?
MS. STOKES: Objection. Form.
THE WITNESS: Yes.
BY MR. JESSEE:
Q. And that's -- basically, as FDA commissioner, you are in charge of enforcing FDCA, right?
A. Correct.
Q. The --
A. I mean, I was the guy who ceased orange juice.
Q. And one aspect, again, and we are now talking about the post-market side of FDA's regulation is medical device reports and the requirements that those must be submitted in certain circumstances?
A. Yes, sir.
Q. And there is actually a MAUDE

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database that the FDA keeps of these medical device reports that anyone can go and search?
MS. STOKES: Objection. Form.
THE WITNESS: And I have done that for medical devices.
BY MR. JESSEE:
Q. You did that for the -- which devices did you do that for?
A. I did that -- I don't want to say I did it for everything. Actually, I did do it for each of the devices in my report, I think, but I only searched for -- I searched -- so I searched deaths and your devices.
So I did it for each of the devices in my report, the number of deaths and death reports.
Q. And you understand that the FDA's -- that MAUDE database -- there is a number of statements on the web site about the limitations of that data?
MS. STOKES: Objection. Form.
THE WITNESS: As you would expect in

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any kind of adverse event reporting, there are statements on the error system, and there are statements on the adverse -- the MAUDE database.

BY MR. JESSEE:

Q. I mean, with those statements, instead of me going through each of them, would you -- are there any that you disagree with the limitations on that data?

MS. STOKES: Objection. Form.

THE WITNESS: As an epidemiologist, I would -- we could probably, on each one of those, spend an hour, if you had to pull up the specific ones, because they tend to be generalities.

And I think I know -- I certainly know the ones in a drug sense almost by heart, but this is -- on the MAUDE data sheet, I use it, and I use the pulldowns.

If you want to talk about a specific one, I'm happy to.

BY MR. JESSEE:

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Q. Okay. And you realize that there is certain -- that they don't establish -- based on just what you see, the complaints in the MAUDE database aren't going to establish causation, for example, right?

MS. STOKES: Objection. Form. Argumentative.

THE WITNESS: Maybe yes and no would probably be the right answer to your question. I mean, you know -- I mean, it's not rocket science as it is.

Sometimes you take a drug. You develop a heart attack. There is a high incidence of -- there is a background incidence, a heart attack.

You have a mesh. It's in the intestine. It perforates the intestine. There is not a question of causation there.

So you have to be more specific when you talk about causation, I mean, and what -- and sometimes medical devices is easier, right?

I mean, the device has migrated.

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It's not in the right place. You don't need epidemiology to be able to do that. So it depends on the question you are asked.

BY MR. JESSEE:

Q. Well, let's just look at the web site page then.

A. Okay.

MR. JESSEE: What number are we on?

THE REPORTER: 21.

(Deposition Exhibit 21 was marked for identification.)

BY MR. JESSEE:

Q. Dr. Kessler, this is something -- this web site page, you have obviously seen before.

A. Correct.

MS. STOKES: Objection. Form. Foundation.

MR. JESSEE: About him seeing it before?

MS. STOKES: This exact --

THE WITNESS: There's actually

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pulldowns, I think, on the event type. This doesn't quite capture the screenshot. I think there is pulldown menus, etc., but it's pretty good.

BY MR. JESSEE:

Q. And I will represent to you I printed this off yesterday.

A. But you know for event type there is a little arrow there.

Q. Right. And that's just when you are printing.

A. Exactly. That's the only point I am making.

Q. Okay. And it notes in here that there are limitations, like we said, to this passive surveillance system, right?

MS. STOKES: Where are you -- objection. Where are you talking about?

THE WITNESS: So it's passive with regard to users and physicians. It's not passive when it comes to manufacturers.

BY MR. JESSEE:

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Q. Okay. And let's see. I am reading the second paragraph, where it says --
A. Tell me which paragraph you're at.
Q. Second.
"Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone, due to underreporting of events, inaccuracies in reports, lack of verification that a device causally reported event, and lack of information about frequency of device used."
Do you disagree with any of that?
MS. STOKES: Objection.
THE WITNESS: I am happy to discuss every single parenthetical with you.
BY MR. JESSEE:
Q. My question is, do you disagree with that statement that is on FDA's web site there?

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MS. STOKES: Objection. Form.
THE WITNESS: Yes. I mean, I don't think all of it is accurate. I think there is nuances to each parenthetical that I am happy to discuss with you.
BY MR. JESSEE:
Q. Let's go down then. I want to look at the third bullet point, where it says -- I'm sorry. Let's look at the second bullet point, where it says, "MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between the devices."
Would you agree with that statement?
MS. STOKES: Objection. Form. Compound.
THE WITNESS: So, I mean, there is a lot of truth in that statement. There are pharmacovigilance tools that have developed that involve -- as long as you use the word alone, I would agree with you in general part, but there are very sophisticated statistical

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modeling tools that do allow you to use databases to compare one versus the next.
Now, that is not this data alone, but that would be -- I mean, people have spent their -- I mean, there are statisticians who are expert in world class, and there is methodology to do that.
BY MR. JESSEE:
Q. Would you agree that to establish a complaint rate though, you can't just look at the complaints in isolation? You have to look at the total number of uses of the device?
MS. STOKES: Objection. Form.
THE WITNESS: I would even go one step further. I mean, because of the underreporting of -- in general, you are not going to get a true incidence rate. You can get a relative incidence rate.
There may be useful information that you can pull by using those models, but that's what pharmacovigilance -- pharmaco device vigilance experts spend their careers working

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on.
BY MR. JESSEE:
Q. Do you represent yourself to be a pharma -- what was that phrase you used?
A. Yeah. I have been specially trained. I think that -- and I am a professor of statistics. I tend to allow some of the statisticians to actually do the run, but I have been specially trained, and I did the MedWatch program.
Q. Right. But you didn't do that analysis in this case though, right?
MS. STOKES: Objection. Form.
THE WITNESS: I did not. I don't think I rely on the incidence rates. There may be some discussion. We talked about an infection, as far as notice of a higher infection rate in the report, but I don't -- that's where it comes up, I believe.
BY MR. JESSEE:
Q. Do you know the total number of devices Bard has sold for any of the -- and I

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am trying to say the -- when I say just maybe the subject devices, I'm referring just to the PerFix Plug, Ventralex.
A. You know, I --
MS. STOKES: Objection. Form. Vague. Speculation.
BY MR. JESSEE:
Q. I am happy to go through the whole list for you, Doctor, but do you know what I'm referring to? The PerFix Plug, the Ventralight ST, Ventralex, PET and PDO, and the 3DMax.
My question then is, do you, for those subject devices, know the total number of units that Bard sold of each of those?
MS. STOKES: Objection.
THE WITNESS: I mean, there are sheets that I can pull that do have that data at different points in time. And, again, it's a little -- it's not just implant -- is it implanted? Is it sold? Is it on shelves?
Much of the Bard data is in terms of revenue, but, certainly, in units sold.

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BY MR. JESSEE:
Q. It's not in your expert report, as far as the number of units sold?
A. I'm certainly aware that that would be -- that's potential denominated data, but, again, because there's such underreporting, in general, in medical devices, you focus on complaints.
I mean, when I do quality control, I mean, the FDA certainly wants MDR reports, but it's really the trend you want to focus on. Because there is a vast underreporting in general, you tend to focus on complaints.
Q. Let's talk about 510(k) for a little bit. I want to look at Page 10, Paragraph 31 of your report.
A. Happy to do that.
Q. Basically, you set forth a standard that substantial equivalence means that the device is at least as safe and effective as the predicate, correct?
THE WITNESS: He does talk fast.

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MS. STOKES: What page are you on?
MR. JESSEE: Paragraph 31, Page 6.
THE WITNESS: That's why I am in processing.
Page 31.
MS. STOKES: Page 10.
THE WITNESS: Page 10, Paragraph 31. And the definition that you are quoting from is which paragraph? Paragraph 31.
BY MR. JESSEE:
Q. Paragraph 31.
A. Yeah. I think that's fair.
Q. Let's look at Page, this time, 38, Paragraph 103.
A. Correct.
Q. All right. In that paragraph, you state that, "Obviously, FDA's review has an eye towards" --
A. Wait a second. I'm on Paragraph 38.
Q. We're getting a little confused here. This is Page 38.
A. Sorry.

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Q. That's all right.
A. I'm sorry.
Q. 103 is the paragraph.
Dr. Kessler, in that paragraph, you state that, "Obviously, FDA's review has an eye towards safety and effectiveness, and FDA will identify information that appears to be false or misleading."
That's your statement in your report, correct?
A. Correct.
Q. And while the standard of review is certainly different and is not a finding that the device is safe and effective though, safety and effectiveness does factor into the FDA's review.
It's on the reviewer's mind, right?
MS. STOKES: Objection. Argumentative. Form.
THE WITNESS: How much time do you have?
BY MR. JESSEE:

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Q. Well, can you answer that yes or no? Does safety and effectiveness factor into the FDA's review?

MS. STOKES: Objection.

THE WITNESS: You asked me whether it had an effect on someone's mind.

BY MR. JESSEE:

Q. That is maybe a poor thing, but you say here that it has an eye towards safety and effectiveness.

What do you mean by that?

A. The standard, as you cite -- cited me correctly, is, are you as safe as something on the market?

Q. That's a substantial equivalence?

A. Yeah. So the whole premise, the whole statute was based on, okay, especially when you went through these classes, this whole Class II, and if there is stuff on the market that were grandfathered, if you are as safe as something that's already on the market and that was determined to be safe, right, then we are

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okay. That's the hope.

The problem is, if you are as safe as something on the market, but you never established safety to begin with, how is that okay?

So there is major criticism and controversy, but the law is the law. And FDA is stuck with substantial equivalence.

And so FDA, because -- not just me saying it, but the National Academic of Sciences. The IOM has said it. FDA has come under substantial criticism for allowing devices to get on to this market without a thorough -- without a safety and effectiveness review under this -- where safety and effectiveness was never established.

So to do that, you see at different points in time -- you see it most recently, I think, in Commissioner Gottlieb in 2018, 2019, the last set of reviews, Okay. We're going to fix that. We're going to try to incorporate more -- if we see a safety problem, meaning

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substantial equivalence, if something comes to our -- we will try to do more to establish safety and effectiveness.

The problem is, you are trying to put a round hole in a square peg, because the standard is, you are as safe as something already on the market, not that there is independence.

So there is elements where you see FDA sometimes doing a de novo 510(k), where you say, Okay. You can come on the market under the 510(k), but you have to do human clinical trial.

No one did that here, for example, on the Composix mesh. It was supposed to be as safe as something on the market, but it was a new use, and no one said you could, under the 510(k) process, have said here, Well, we're going to put this in the intraperitoneal, and no one put peritoneal -- a polypropylene and ePTFE together in the abdominal cavity. That's a new issue. We have not established the

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safety. So let's do a de novo clinical trial and do that under the 510(k) process.

Q. So the FDA actually requires clinical trials for some 510(k) devices, right?

A. It can.

Q. And it does. It does for IVC filters, for example. It requires clinical trials for quite a number of those, doesn't it?

MS. STOKES: Objection. Form.

THE WITNESS: Again, what kind of clinical trials, et cetera?

BY MR. JESSEE:

Q. My question though is that it does require clinical trials for IVC filters. And I have seen you testify to it, and I have seen --

MS. STOKES: Let him answer. Same objection also.

THE WITNESS: At different points in time, there may have been certain human studies done. I don't believe in Bard IVC there were adequate and well controlled clinical trials that were required.

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BY MR. JESSEE:
Q. That wasn't my question though. It is not just for Bard's IVC filters have been -- clinical trials have been required. There is -- it can require -- the FDA has the power to require those clinical trials, both premarket and postmarket, don't they?
MS. STOKES: Objection. Form.
THE WITNESS: Again, I'd have to look at the statute. The FDA has moved towards the point where it says, In certain instances, we're going to require more in the 510(k) process to give the public confidence.
BY MR. JESSEE:
Q. And there's certain information that is submitted in the 510(k) process that goes to safety of the device and irrelative to the safety and effectiveness of the predicate.
Would you agree with that?
MS. STOKES: Objection. Form. Argumentative.
THE WITNESS: Yeah. I think that's

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fair. I mean, it has to be as safe as the predicate.
BY MR. JESSEE:
Q. Right. So like biocompatibility testing, for example, that is not necessarily -- often in 510(k)'s from implantable devices there will be biocompatibility testing for that device submitted with the 510(k), correct?
MS. STOKES: Objection. Form.
THE WITNESS: Well, biocompatibility should be done as part of the GMP of all 510(k). I mean, there should -- but that doesn't tell you -- that is questioning genicity, reproductive, tox --
That's not clinical testing. That's not telling you whether the device is going to move, it's going to perforate. It's going to end up somewhere it shouldn't. That is not biocompatibility testing.
BY MR. JESSEE:
Q. And I wasn't suggesting it was. I'm saying though that is one piece of the puzzle.

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That is safety data, biocompatibility testing, isn't it?
MS. STOKES: Objection. Form.
THE WITNESS: Sure. That is standard carcinogenicity, reproductive, certain mechanical testing, but that gets to the whole point.
Those things don't go to, really, the kind of clinic -- those don't go to the major clinical questions that -- you know, that you would get out of a human trial.
BY MR. JESSEE:
Q. On Paragraph 104 of your report you state that: "In my opinion, the information required and not required to support a 510(k) application is appropriate for the 510(k) process because that process evaluates substantial equivalence, specifically, whether a device is as safe and effective as the predicate device and if it raises new questions of safety and effectiveness not present for the predicate."

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Is that statement still accurate today?
A. Let me just read.
MS. STOKES: Which paragraph were you just reading from?
MR. JESSEE: 104. Just the next one down.
THE WITNESS: Yeah. So what this means is that -- just so I can make sure everyone -- that I am clear here, is what is meant when FDA says it's going to -- the number of times where FDA has upped the scientific requirements of the 510(k) or even required de novo clinical trials, those de novo clinical trials are the result -- I mean, they are not to determine independent safety and effectiveness, but if you read FDA, they are saying their authority to require those clinical de novo clinical trials are to determine whether that a new device raises new questions of safety and effectiveness and goes to substantial equivalence. That's the

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authority.
BY MR. JESSEE:
Q. The premarket authority you are talking about?
A. That's the premarket -- the authority to require de novo 510(k).
Q. Right. With clinical studies though --
A. De novo clinical studies. Those clinical studies are not -- FDA doesn't have the authority to require them to establish independent safety and effectiveness.
FDA has an ability to require those studies to determine whether it's substantial equivalence. That's what I mean in that statement.
Q. We are talking about premarket clinical studies in that context, because the FDA has the authority to require postmarket clinical studies as well?
A. It has 522 orders, yes. I mean --
Q. And it can order those for

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implantable devices over a year. It has the authority to order those?
A. And has done those. For example, in other contexts and other types of mesh, FDA has done that.
Q. But not in any of the Bard mesh products, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Not that I am aware of. It has done that in other kinds of Bard mesh products.
MR. JESSEE: All right. I'm going to go ahead and mark Exhibit 22.
(Deposition Exhibit 22 was marked for identification.)
BY MR. JESSEE:
Q. I'm not going to spend much time, because I know you were asked about this a lot, and I know you are familiar with it, but this is the FDA's 2014 guidance on the 510(k) program, evaluating substantial equivalence and premarket notifications.

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A. Sure.
Q. And this is something I know you are very familiar with.
A. Sure.
Q. And you will not be surprised to know I have read a bunch of your testimony on this, including stuff as recently as last year about -- you agree with the statements in here that the safety and effectiveness factor into the FDA's review of 510(k)s, right?
MS. STOKES: Objection. Form.
THE WITNESS: I would phrase it the way I have phrased it in the report and the way I have talked about. I think there is -- there is an element -- there is an element of that. I think FDA tries to incorporate that, but in the end, it's substantially -- a substantial equivalence standard.
BY MR. JESSEE:
Q. So, for example, on Page 6 -- and, again, I'll be happy to show it to you. I know you've read these. You have been asked about

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these and read this extensively, but it says: "The principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."
A. Yes. But you are reading a portion of this, and there's other portions, but in the end, it is a substantial equivalence determination. That's not changed. You have to be as safe as something already on the market.
Q. You mean -- I'll read the sentence before it.
"The 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness."
A. Show me where you are. I apologize.
Q. Right here in the statutory standard.
A. Thanks.
Q. I will try to slow down while I'm reading this too. I apologize.

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"The 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness. Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."

Do you agree with those two sentences?

MS. STOKES: Objection. Form.

THE WITNESS: As generalities, I think that they -- I think that's aspirational.

BY MR. JESSEE:

Q. So you don't believe that that is accurate, that statement in this FDA guidance?

MS. STOKES: Objection. Asked and answered.

THE WITNESS: I think it's -- the answer is yes and no. I think it's aspirational. I think that is what FDA would like to be able to think. I think there is substantial limitations of substantial

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equivalence, because that's the statutory standard.

So you are trying to put -- either the standard is, you have to be as safe as something on the market or you got to be safe and effective.

And you can't make 510(k) into an independent determination as safe and effective. The statute doesn't -- that is not what the statute says.

So FDA is constantly criticized for letting these devices on the market without independent safety and effectiveness, and it gets beaten up.

So it says, Well, we have an eye towards safety and effectiveness, but, again, it's more complicated than any one sentence would have you -- that you can capture in one sentence.

BY MR. JESSEE:

Q. The -- you say in your report that the 510(k) has undergone a number of statutory

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changes since its inception.

Do you agree with that?

A. Well, we've talked about 1990 --

Q. That was one -- the big one, right?

A. That was -- exactly.

Q. The -- and do you agree that the -- over the past decade the 510(k) reviewed has become more stringent?

MS. STOKES: Objection. Form.

THE WITNESS: Over the last decade, I'm not -- depends on what metric you use. I think that the answer -- it would depend on the individual review division. The -- the answer's probably not. Because in the end you see when -- when did Gottlieb say, "Hey" -- he basically, you know, caved in 2018 and 2019. And he said -- and said, "Look, we -- this -- this process has not worked."

I mean he didn't quite go that -- I mean -- but -- but he basically said -- I'm saying the ION come -- came out, said, "510(k) has to be changed. It's not working. It's not

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an independent assurance to safety and effectiveness."

FDA fought that. It did this in 2014. It issued this guidance. In 2018 there was -- 2018, 2019, there was a plan. And right before Scott left, there was a -- basically saying, "Look, we have to -- we have to figure out how to change the whole process."

So there -- there were -- there were some changes over time. But I think it's -- I don't think it's fundamentally different over the last decade.

BY MR. JESSEE:

Q. And you previously testified that -- and I think we can agree that the FDA can ask for additional information when reviewing 510(k)s, and they -- they often do, right?

A. Fair.

MS. STOKES: Objection. Form.

BY MR. JESSEE:

Q. And I think your -- in specific words I found, you said that you rarely see

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510(k) that the FDA asks no questions whatsoever.

MS. STOKES: Objection. Form.

THE WITNESS: That may be and over -- I wouldn't wanted to say "never." But --

BY MR. JESSEE:

Q. I think "rarely" is the -- the word.

A. Yeah. I -- I think -- I think that would be fair.

Q. Okay. The -- did you review the Federal Register proposed rule for -- from 1982 related to a surgical mesh?

A. The classification?

Q. Yeah. The proposed classification?

A. I -- at some point in time. It's ringing a bell. Because it wasn't just hernia mesh, I believe, right?

MR. JESSEE: Yep. We'll take a look at it.

Let's actually -- let's take a couple-minute break so I can get my documents in order.

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THE VIDEOGRAPHER: We are going off the record.

This is the end of Media Unit No. 3.

The time is 2:01.

(A short recess was taken.)

THE VIDEOGRAPHER: We are going back on the record. This is the start of Media Unit No. 4.

The time is 2:21.

(Deposition Exhibit 23 was marked for identification.)

(Deposition Exhibit 24 was marked for identification.)

(Deposition Exhibit 25 was marked for identification.)

(Deposition Exhibit 26 was marked for identification.)

BY MR. JESSEE:

Q. Dr. Kessler, I'm going to hand you a few exhibits, ask you questions about them.

The first one is going to be the Federal Register that I referenced about the

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classification of surgical mesh as a Class II device.

The second one is going to be a document -- and FDA web site on hernia surgical mesh implants.

And this is -- you've reviewed this on the FDA web site, correct?

And let me --

A. Yeah.

Q. And -- I'm sorry.

You have?

A. Yes.

Q. And just --

A. I -- I reviewed this. I don't know which version. I assume this is the current version.

Q. Yeah.

A. Yeah. I've seen that.

Q. Okay. And I -- just for the record, the first -- the Federal Register document I handed was Exhibit 23. The FDA remember web site on hernia mesh is Exhibit 24.

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I'm now handing you Exhibit 25, which is the FDA activities --

A. Let's -- I want to make this look a little better.

Q. FD --

A. 127.

Q. FDA activities on the urogynecological mesh. And this is, again, from the FDA website.

And then Exhibit 26 is the Guidance for Preparation of Premarket Notification Application for Surgical Mesh.

And this is --

A. This is --

Q. -- Exhibit --

A. -- the '99 document.

Q. Yes.

A. Sure.

Q. And these are all documents that you've reviewed?

A. At different point in time.

Q. Okay. Let's focus on the Federal

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Register classification. And if you could, please, sir, it's on Page 2817 of the Federal Register where it discusses the panel and FDA's finding and classification of surgical mesh.
A. Correct.
Q. And do you see generally where that starts at the bottom of the first column?
A. FDA agrees? Is that what -- 2817?
Q. I'm looking at the Section 878.3300, the bottom of the --
A. I'm sorry.
Q. -- left-hand column.
A. Page 2817?
Q. Yes. 2817.
A. 7. Bottom of --
Q. Left -- left.
A. Right. Left column, Section 873 [sic]. Okay.
Q. Right.
A. Surgical mesh.
Q. And in this Federal Register, there's a number of different device

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classification panels that make a recommendation to the FDA on what classifications surgical mesh should be.
MS. STOKES: Objection. Form.
MR. JESSEE: And, Doctor, if we need to take -- go off the record again so you --
THE WITNESS: No. It's just --
MR. JESSEE: -- can take that, it's fine.
THE WITNESS: That is actually a -- a patient. But I --
MR. JESSEE: I'm more than happy to stop and let you take that. Why don't you --
THE WITNESS: Let -- let --
MR. JESSEE: Let's go off the record, please.
THE WITNESS: That -- that -- that's all right.
MR. JESSEE: You sure?
THE WITNESS: That's -- it's going to be a patient, but that's --
MR. JESSEE: I certainly --

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THE WITNESS: No, no, no, no --
MR. JESSEE: -- by no means want to interrupt --
THE WITNESS: -- no, no, no. That's not what --
THE VIDEOGRAPHER: We are going off the record.
The time is 2:24.
(A short recess was taken.)
THE VIDEOGRAPHER: We are going back on the record.
The time is 2:26.
BY MR. JESSEE:
Q. Doctor, in the 1982 Federal Register discussing the classification of surgical mesh as Class II, in the middle column you'll see at the top of the page they give examples of surgical mesh. And one of them is metallic and polymeric mesh for hernia repair.
Do you see that?
A. Correct.
Q. And in this Federal Register, the

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FDA actually discusses specific articles looking at hernia repair, right?
A. Sure. It -- it -- it -- it has a record of the -- based on the clinical views back in the '80s.
Q. Okay. At that time in 1982 polypropylene hernia mesh had been on the market for quite a while, right?
MS. STOKES: Objection. Form.
THE WITNESS: Several decades.
BY MR. JESSEE:
Q. The -- if you look in the middle column again, the panel -- the panels that -- the FDA advisory committee panels recommended Class II, and they state that --
A. You're -- you're -- you're -- just show me where you are. I'm sorry. You're --
Q. Sure. Middle column where it says "Recommended classification Class II."
A. So I'm on middle column, No. 4? No. 3?
Q. No. 2.

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A. No. 2. Thanks.
Q. Yep?
A. Thank you.
Q. And this is generally how these work, right, the federal registers, is that they'll say the -- the panel's recommendation for the classification, and then the FDA can either agree or disagree, right?
A. Correct.
Q. And here the panel states -- and I'm looking at No. 3 now, that they say the panels believe the device has an established history of safe an effective use.
Do you see that where I am?
A. The panels recommend that surgical mesh be classified, believe the materials used in the device should -- should meet a generally accepted -- give me wherever you are.
Q. The -- in the --
A. Panels believe that general controls alone would not --
Q. Yep. Right before that.

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A. Sorry. The orthopedic device panels recommend acetabular mesh --
Q. So if you look at No. 3, Doctor.
A. Yeah. I'm in 3.
Q. "Summaries of reason for recommendation."
Do you see that?
A. Just hold up yours so you can show me.
Q. Right -- right where the No. 3 is.
A. Okay. Summary of reasons. Yeah.
Q. Yeah. And they say --
A. Sorry.
Q. -- "Panels recommend that surgical meshes be classified as a Class II performance standards. Does the panels belive the device has an established history of safe and effective use?"
Do you see that?
A. Correct.
Q. The -- and if you go down a little bit, about halfway down that paragraph, it talk

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-- states: "Although this device is an implant" -- do you see where I'm reading, Doctor?
A. Right.
Q. I'm sorry. Did you --
A. I'm there. Sure.
Q. Okay. "Although this device is an implant, the panels believe that premarket approval is not necessary to provide reasonable assurances of the safety and effectiveness of the device."
A. Uh-huh.
Q. See that part.
And that's the panel's conclusion?
MS. STOKES: Objection.
THE WITNESS: For --
MS. STOKES: Form.
THE WITNESS: For that device, for its in -- as its -- for the intended uses for the way it was being used back in the '80s.
BY MR. JESSEE:
Q. Yeah.

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And so in No. 4 here, it states -- you see "The summary of data on which the recommendation is based"?
And this is the panel's recommendation?
A. Right.
Q. It states: "The panel based their recommendation on the panel members' personal knowledge of and clinical experiences with" --
A. I see that.
Q. -- "the device and on a review of the literature"?
A. Correct.
Q. And if we go farther down on this -- in the same column, it -- we get the FDA's position on the classification of surgical mesh, right?
A. FDA agrees?
Q. Right.
And that's that -- where it says "The FDA agrees that the panel's recommendations"...

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Do you see that part?
A. Right.
Q. And the next sentence states: "Although the device is an implant, the agency believes that premarket approval is not necessary because of the extensive clinical usage of surgical mesh over a long period of time and because there is sufficient information available to establish a performance standard that would provide reasonable assurance of safety and effectiveness of the device"?
A. As it was being used back then. That's not the issue here.
Q. And it was being used back then as a polypropylene --
A. Flat --
Q. -- mesh, right?
A. -- mesh.
MS. STOKES: Objection. Form.
THE WITNESS: I mean -- well, first of all, this was flat mesh. You didn't have

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composite meshes. You didn't have plugs. You didn't have intended uses interabdominal [sic]. This is just surgical mesh. This is flat mesh back then.
No -- no one's saying -- and -- and all this says is, if you are as -- you have to be substantially equivalent to -- this allows it to be Class II, which says you got to be the same as that flat mesh.
If you have a different intended use, if you raise new safety questions, you can't -- none of that -- this applies.
BY MR. JESSEE:
Q. Do you see where it says the FDA has reviewed pertinent clinical literature on surgical meshes?
A. Sure.
Q. And that's something we can agree: The FDA's reviewed clinical literature on surgical mesh a number of occasions, right?
MS. STOKES: Objection. Form.
THE WITNESS: As.

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MS. STOKES: Argumentative.
THE WITNESS: This was based on how the device was used back in 1982. And if the devices were the devices -- the same as the devices in 1982, I don't think we would be sitting here.
BY MR. JESSEE:
Q. Do you know if the FDA has reviewed clinical literature on hernia mesh more recently?
MS. STOKES: Objection. Form. Vague. Calls for speculation.
THE WITNESS: I can tell you there is -- there's -- sometimes there's literature. We'd have to go through each 510(k) and each medical officer review.
BY MR. JESSEE:
Q. Okay. And I have an easier way we can do it here.
But the -- looking just at here though, we -- we mentioned there's actual citations to specific references here in

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literature?
A. Sure.
Q. Do you know how many of these deal with the Bard Marlex mesh?
A. I -- you can count them. I have not counted them.
Q. Have you reviewed the literature that the FDA cited in the classification -- proposed classification in 1982?
A. I looked at a number of studies historically. I -- I've not necessarily looked at this bibliography. But as you know, I've cited -- I've looked at a lot of the literature historically.
Q. Let's look at -- take a look at Exhibit 24, which is the hernia surgical mesh implants web page on the FDA web site.
A. Right.
Q. And the FDA often includes information about categories of devices on its web site, right?
MS. STOKES: Objection. Form.

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THE WITNESS: Sure. Because it's -- absolutely.
BY MR. JESSEE:
Q. And the -- if you would look at the second page -- bottom of the second page where it says: "Hernia repair surgery complications."
A. Hernia -- treatment options for hernias?
MS. STOKES: Second page.
THE WITNESS: Sorry. Apologize.
MR. JESSEE: It's all right.
THE WITNESS: Right.
BY MR. JESSEE:
Q. The -- it states: Based on FDA's analysis of medical device adverse event reports in a peer-reviewed scientific literature, the most common adverse event for all surgical repair of hernias, with or without mesh, are pain; infection; hernia recurrence; scar-like tissue that sticks together; adhesion; blockage of the large or small

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intestines, instruct -- obstruction in parentheses; bleeding; abnormal connection between organs, vessels or intestines, fistula in parentheses; fluid buildup at the surgical site, seroma in parentheses; and a hole in neighboring tissues or organs, and then perforation in parentheses.
Do you see that, Doctor?
A. I see that.
Q. And you -- you would agree that the FDA has, in relation to hernia repair, reviewed scientific literature?
MS. STOKES: Objection. Form.
THE WITNESS: That -- that's what this document says. We don't have -- I -- I wouldn't want to jump -- I've not seen a document from FDA -- and maybe you have and can show it to me -- of the FDA's review of scientific literature on this.
I have not seen a White Paper or -- on hernia literature. So I've not seen that.
BY MR. JESSEE:

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Q. Would you expect the FDA to falsely state that in their -- on their web site?
MS. STOKES: Objection. Form. Argumentative.
THE WITNESS: I -- you -- you have my answer. I mean -- I mean I don't expect FDA to falsely state something. But whether this was based on a comprehensive scientific literature review, it depend -- I mean I haven't seen that comprehensive, nor has FDA put that out. That's all I'm saying.
BY MR. JESSEE:
Q. You'd agree that, in the 510(k)s for the subject devices in this litigation, that there were clinical literatures submitted with several of them?
MS. STOKES: Objection. Form. Vague.
THE WITNESS: I think that's generally true. There's literature cited, not necessarily always comprehensive. And that's based on the man -- what the manufacturer does.

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But again, most of -- we'd have to go through 510(k) by 510(k). Some of the initials -- again, the -- the -- the -- the focus is on are you the same as something on the market.
So most of the paragraphs are on substantial equivalence. It's not on a comprehensive literature review. But we can pull them up and look at them individually if you want.
BY MR. JESSEE:
Q. And does that say in that -- anywhere in the -- this document talk about substantial equivalence?
MS. STOKES: Objection. Form.
THE WITNESS: You -- you can --
MS. STOKES: You just gave it to him.
MR. JESSEE: No. And he's reviewed it before.
THE WITNESS: Yeah. I -- the -- the -- I don't think substantial equivalence is --

I mean is the kind of -- when you're talking to the public, you know, talking about substantial equivalence is not something FDA, you know -- FDA doesn't say that here. That's not the purpose.

These are the kinds of sheets that, you know, hospitals put out on certain -- in certain areas to give some general information.

BY MR. JESSEE:

Q. And do you agree with the FDA's -- what they list, based on their review of adverse event reports in peer-reviewed scientific literature, the most common adverse events for all surgery -- surgical repair of hernias with or without mesh?

MS. STOKES: Objection. Form.

THE WITNESS: I -- I --

MS. STOKES: Compound.

THE WITNESS: Again, I would -- certainly I don't -- I would not agree -- I'm prepared to talk about the -- the adverse event profile per device. I mean I -- this

amalgamation I have not issued one set of adverse events for all --

BY MR. JESSEE:

Q. Okay. Give --

A. -- lots of -- it depends on the hernia mesh, I think. And I'm -- I'm --

Q. Something surgeons would talk about then? The --

A. Sorry?

Q. Something that we -- the surgeons could answer then, that question, whether this is the accurate description of the --

MS. STOKES: Were you done with your answer, Doctor?

THE WITNESS: No. I -- I'm happy to tell you what the answer -- it doesn't list chronic pain. Chronic -- I would disagree with this. Certainly when it comes, as you know, to the PerFix Plug and 3DMax, chronic pain should be listed.

Migration should be listed. I don't need the surgeons to tell me that. This is

from your own documents. Those things should be listed.

But again, this is a general statement. This is not -- all I'm saying is this is not product by product. This is -- some PR, public affairs person probably put this together.

BY MR. JESSEE:

Q. You're -- you're speculating on that, right?

MS. STOKES: Objection.

THE WITNESS: No. I'm -- I'm pretty good at -- I mean -- the -- the --

BY MR. JESSEE:

Q. All right. Who -- what do you base on who wrote this on -- who wrote this?

A. Because I know who -- I mean at least in -- in my history of public affairs and FDA, these are the kind of things FDA tends to do, the -- the public affairs --

BY MR. JESSEE:

Q. Back when you were commissioner in

1990 --

A. Yeah. I mean --

Q. -- to 1997?

A. -- I -- we -- we -- we can determine who -- which division. But this is not specific. This is not the medical review officers who are writing this.

Q. All right. Let's look at Exhibit 25, which is the summary of the FDA's activities on urogynecological surgical mesh.

A. Correct.

Q. And you're familiar with all these activities, right?

You've offered opinions on them in the past?

A. I --

MS. STOKES: Objection. Form. Compound.

THE WITNESS: I'm not sure I've offered opinions on every single one. I'm certainly familiar with this document. And I hope to forget this document.

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BY MR. JESSEE:
Q. Yeah. And this document that talks about -- you would agree there is a number of activities the FDA took with respect to -- to urogynecological surgical mesh, correct?
A. Correct.
Q. They convened -- they issued two public health notifications?
A. They did.
Q. They convened an advisory panel to review the --
A. Correct.
Q. -- urogynecologic meshes?
A. Correct.
Q. They required 522 studies for classes of these devices?
A. Eventually.
Q. And those being post-market clinical studies, right?
A. Correct.
Q. They end up reclassifying surgical mesh devices for pelvis organ prolapse from

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Class II to Class III, requiring PMAs?
A. Right.
And?
Q. And they ended up eventually taking them from the market, right?
A. They pulled the -- all the products from the market, right?
Q. Right?
A. So -- so -- but at an earlier stage, FDA had certain pages where they didn't have all this.
Q. Yeah.
And these -- those -- for those pelvic organ prolapse mesh products, those came on the market in the 1990s beginning and then passed -- and that was the earliest ones on the market?
MS. STOKES: Objection. Form.
THE WITNESS: You have those in your head. I don't have the history.
BY MR. JESSEE:
Q. Okay. And you're --

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A. It's my -- no, no. I -- I certainly leave it to your expertise on --
Q. And I actually --
A. -- on POP.
Q. And you did a report on it. So it's --
A. No, no. I mean we -- we don't disagree. I just don't have --
Q. Okay.
A. -- it in my head.
Q. But can we agree that, with all the activities we just talked about that the FDA took with respect urogynecological surgical mesh, they did -- have not taken any of those activities with respect to hernia mesh?
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. And that's a simple question.
Have they taken any of those activities with respect to hernia mesh?
MS. STOKES: Objection. Form.
THE WITNESS: The answer is no.

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BY MR. JESSEE:
Q. Okay. The --
A. I'm --
Q. I thought you were done. I'm sorry.
A. No, no. The -- the answer is no. But understand that they spent -- they had an enormous problem, I mean I think over -- we span, what five years, probably longer, eight years, nine years -- actually, this was eight years where they were saying -- basically they were -- if I remember, they weren't safety questions back in '08 -- I mean, if you look at the FDA web site.
It was a difficult period of time with regard to urogynecological meshes that ultimately left -- led to withdrawal. So it took them a decade to get there. They -- and that took an enormous amount of energy from the agency.
And there's only so many -- and that was -- to its credit, that's what it -- it got to the right answer. And -- but it took a

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decade. And it -- it took a lot out of the agency to get there. And there's only certain amount of resources the agency has on what it's focused on.

Q. The -- you mentioned earlier silicon breast implants. And that was something that occurred when an issue -- a controversy occurred while you were a commissioner of the FDA, 1990 to 1997.

And you actually took action with respect to silicon breast implants, correct?

MS. STOKES: Objection. Form.

THE WITNESS: I did.

BY MR. JESSEE:

Q. And you issued a -- a final rule was issued calling for PMAs for silicon breast implants in 1991, right?

A. Please do the studies. Yes.

Q. And in January 1992, you requested a moratorium on sales of silicon breast implants except for certain circumstances?

A. It was basically a time-out until

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those studies were done.

Q. Okay. And then these -- those implants were subsequently limited to access to silicon breast implants except -- or -- for cosmetic purposes to clinical trials, right?

A. Correct.

Q. And --

A. Except for cosmetic the purposes. I mean it -- it was -- it was always allowed in -- for cancer patients. And again, certain types -- these were silicon.

Q. So we can -- can we agree on a basic level that there -- there are instances where the FDA has taken action when they have seen concerns with safety of medical devices that are -- even medical devices classified as Class II?

MS. STOKES: Objection. Form.

THE WITNESS: So sure. But understand -- and that action -- just so the record's fully clear, we now know those silicon breast implants are associated with certain

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cancers, right?

So I mean we didn't know exactly the science. We pushed for that science. And now we -- we know that there are -- those risks are very real with regard to causing cancer.

My point -- the -- I agree with you, Counselor, that FDA can. But there's a -- there's only so much energy and so much resources and focus that the agency can do.

I can tell you, once we were focused on breast implants, it didn't allow us to focus on something else at that same time. It -- it just takes enormous amount -- I mean I don't want to over -- that's -- that's probably a bit of an overstatement. There's only so many devices you can focus on like that.

So I mean urogynecological, the women's health issues, putting mesh in the pelvis I mean certainly correctly preoccupied the agency and should have. But that -- that sucks up a lot of energy.

That does -- don't -- the lack of

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the agency taking action doesn't mean the agency thinks it's fine or has the resources or even knows the full extent of the problem. It -- that's what it learned in urogynecological mesh over the last decade.

BY MR. JESSEE:

Q. Doctor, there is a -- the FDA has regulations that apply to medical device labeling, correct, and you discuss those in your report?

A. They're -- they're modeled after the drug. They were enacted -- they weren't enacted, but there's guidance in 1991. They're -- they're -- they're -- they're modeled after the drug regs.

Q. Okay. And I want to talk about regulations first, and then we can look at the guidances. Because those are -- there's a difference between regulations and guidances, right?

A. Sure.

Q. The regulations are binding,

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correct?
A. Yes.
Q. And the guidances are not binding, right?
A. That's -- that's a fair -- but they usually followed.
Q. Right.
And they offer the -- the FDA's current thinking on a topic.
A. That's what -- exactly. And you're reading from the quotes. You're quoting from the footnotes or whatever.
Q. And one of the regulation -- the regulation for prescription device labeling 21 CFR 801.109?
A. You just have to give it to me. I don't have the number. I mean I -- one point I knew it.
Q. Okay. Well, and it's in your report too. We can look at it there.
A. Yeah. I -- I mean I just --
Q. But it's -- you're familiar with the

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reg -- the -- what they -- what it requires and what it doesn't, right?
A. Yeah. Be a little careful. Prescription labeling in this -- you're talking about the regulations.
Q. Yes. I'm talking about the regulations and the exemption from the -- at -- at -- having to warn patients about --
A. Because it's --
Q. -- specific guidance.
A. -- prescription. So it's a complicated -- it's a complicated statutory maze in some ways.
Q. Right.
And what it says, though, it says that the medical device labeling for these prescription devices, in order to meet the exemption of the directly warning users -- patients, as it says, it must contain information for use, including indications, effects, routes, methods and frequency and duration of administration and any relevant --

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A. You want to just give me the reg. Well, it's in my report.
Q. Yeah. You have it. It's in your report. Do you -- we can --
A. Just give me the paragraph. Can have the right --
Q. Let's see. I know it's in here somewhere. Okay. And I know -- I'm fairly confident it's in your report somewhere. But just to -- 109. Let me see if I can find it.
A. I'll get it.
801.109.
Q. Yes, sir.
A. Thank you, sir.
I should have it in a second. I have it here.
Q. Okay.
A. I have it here, sir.
Q. All right. So this regulation requires information for use, including indications, effects --
A. Well, just -- just -- just read it

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to me. So just -- you're under the A.
Which section are you reading?
Q. I am under --
A. You're under D?
Q. This is C.
A. Thank you, sir.
Q. And This is a -- the section, again, that you had fully discussed in your report.
Are you looking at your report right now or the regulation?
A. I'm looking at the regulation, sir.
Q. Okay. And it talks about them -- that -- the labeling, the information that must be included on the prescription device labeling, right?
A. Right.
Q. And it mentions, among other things, any relevant hazards, contraindications, side effects, precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose which it's intended?

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A. That's the general -- that was the -- again, pre-19 -- I believe that's pre-1976 language.
Q. Okay. And there hasn't been though any regulations to supplement -- to either supplement or replace this regulation, right?
A. It's -- it's -- it's -- it's a pre -- it's a predevice amendment section of the statute.
Q. All right. And it -- it specifically references relevant hazards, contraindications, side effects and precautions, correct?
A. Yes.
Q. And the focus is on sufficient information for physicians using the devices to use it safely and for its intended purpose?
MS. STOKES: Objection. Form.
THE WITNESS: It's a general statement on labeling, yes.
BY MR. JESSEE:
Q. And this -- these -- this labeling

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regulation, it applies to prescription medical devices regardless of what class they are, right?
A. It's -- again, it was -- I believe the statement even pre -- it was amended -- I've studied the -- the history of this. But this -- this goes back -- even though this was amended to include device, this is old language. This is general language that was just sort of updated in '76.
Q. Would you agree that the -- it's important the information in IFU have a medical or scientific basis?
MS. STOKES: Objection. Form.
THE WITNESS: What section of the label are you talking about?
BY MR. JESSEE:
Q. I'm just talking, in the instructions for use, would you agree that information contained in there, it's important to have a medical or scientific basis?
MS. STOKES: Objection.

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THE WITNESS: It's a general -- there's multiple different sections of the label. And so, again, which section are you talking about?
BY MR. JESSEE:
Q. What about when we're talking about warnings?
MS. STOKES: Same objection.
THE WITNESS: I think that the warnings have to talk about any relevant hazards.
BY MR. JESSEE:
Q. Okay. Do you --
A. I mean I think that or potential safety hazards.
Q. Okay. Do you agree that they -- that they have to have a -- that hay should have a medical or scientific basis to be in the warning section?
MS. STOKES: Objection. Form.
THE WITNESS: I think there has to be -- I mean I think it has to either be a

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potential -- it has to be untoward adverse effect, a -- an untoward adverse effect, a potential safety hazard, or an association with an adverse event.
I mean it has to be a -- it -- I mean it has to conveyed the information that is important to a physician to use these devices safely.
BY MR. JESSEE:
Q. Can you answer the question "yes" or "no" whether a -- the warning -- for a warning to be included in -- under FDA standards in a prescription medical device instructions for use, it need to have a medical or scientific basis?
A. I think it has to -- it has to -- I think it should be based -- if it's on a -- if it is a potential safety hazard, right, that has -- you know, I -- within that potential safety hazard has some -- has a basis, right, that's scientific or medical, I think that -- I wouldn't disagree.

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There's specific definitions of safety hazards. And -- and there's reasonable -- there's association with at adverse event. There's -- it -- the statute is very specific on what it -- and the regulations is very specific on what it requires.
Q. The --
A. I mean it should -- it -- I mean it has to be -- has to be -- has to a relevant hazard, right. So -- I mean in -- this -- as far as this language, the language in the guidance I think is potential safety hazard.
Q. Right.
And then to determine whether something's a hazard or not, you have to have valid scientific or medical evidence, right?
MS. STOKES: Objection. Form.
THE WITNESS: Well, if the word is "potential" or -- "potential safety hazard," right, we can discuss what the standard is, right? But --
BY MR. JESSEE:

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Q. And -- and I think you have that in your report, right?
A. Yeah. But I mean if -- it has to be a relevant hazard or potential safety hazard.
Q. Okay. And "potential" is not in the -- in the -- the regulation language, though, right?
A. It's in the -- it's in the guidance.
Q. Right. Okay. More --
A. It's in the labeling guidance. It's -- it's exactly --
Q. Would --
A. It's in the regulations, I believe, for drugs, which has basically been incorporated, I mean, in the --
Q. Well, you say "basically" though.
There's no med -- there's no regulation for medical devices that say that, that uses the relevant.
A. Well, you're going to get into the issue of whether --
MS. STOKES: Objection.

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THE WITNESS: -- misbranding, whether the drugs are also devices. It becomes complicated.
So in general -- well, all -- all drugs were -- all devices were drugs originally under the Act.
MR. JESSEE: Sure. Yeah. Yeah.
THE WITNESS: And you have certain basic -- basic provisions, right? So I mean -- and basically the guide -- the guidelines did copy the drug regs.
BY MR. JESSEE:
Q. So, for example, a device is reasonably associated -- you said a device is reasonably associated with infection, you would have the duty to warn about infection, right?
MS. STOKES: Objection. Form.
THE WITNESS: You have -- you can pull the guidance. If there is a -- a safety --
BY MR. JESSEE:
Q. And I don't -- I don't want to quiz

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you. So I'll just give -- I'll give you this.
A. Yeah. You can -- you can quiz me. It's fine. I mean but if -- it'll -- it'll be quicker if you give me the guidelines.
Q. And there's two of them actually that we had -- so there's two guidances that you referenced. And I'm labeling one as the one from 1989, which we've marked as Exhibit 27.
(Deposition Exhibit 27 was marked for identification.)
MS. STOKES: Is that what you just gave me?
MR. JESSEE: Yep. I'm giving you.
BY MR. JESSEE:
Q. The other one is the Blue Book Device Labeling Guidance we looked over from 1991?
THE WITNESS: Correct. When I was there.
BY MR. JESSEE:
Q. And you're familiar with both these

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and talk about them in your report?
A. Yeah, I do.
Q. And so --
MS. STOKES: You need to and him 20 -- 28 is what you were saying, right?
MR. JESSEE: Thank you. That's the second one.
THE WITNESS: Should we pull up -- which one do you want me to go to, the later one?
BY MR. JESSEE:
Q. Whichever one you need to consult.
I guess, before we look at these, just briefly though, let's look at 27 first, the front of it.
And on the front of the document, the guidance from 1997, it says: This guidance was written prior to the February 27, 1997, implementation of FDA's good guidance practices, GDPs. It does not create or confer rights for any -- for or on any person and does not operate to bind the FDA or the public. An

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alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations or both."
And that's true -- you agree with that, right?
A. Sure. But I -- I think it's fair to say that's general boilerplate that is correct. And it usually more currently is described as it describes the agency's -- not to get subjective, but they use the term "current thinking."
Q. Right?
A. Right. And so that's what --
Q. And -- and that would be what you just said, and that would be true for this guidance as well as the one that the -- the Blue Book memo that we've marked as 28, right?
A. Correct.
Q. Okay. Now, my question was in -- is if a device is reasonably associated -- the use of a device is reasonably associated with infection, is -- is there a duty to worn of

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that?
A. Okay. So --
MS. STOKES: Objection. Form.
THE WITNESS: Okay. So -- so the answer is -- are you talking about a capital W warning or a little W warning? Because you -- you -- you're going to go to two different sections here.
MR. JESSEE: Okay.
THE WITNESS: And let's just go to the -- the labelling guidance may be a little shorter, right, and may be easier to find. So let's take a -- let's take a little W warning. Okay? And let's just go to page -- it just says 814. But I assume everything is Page 814.
Is that just the printout page? No. Page 8 of 14.
MR. JESSEE: Yep.
THE WITNESS: Right?
BY MR. JESSEE:
Q. Where we talk about adverse reactions?

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A. Yeah. So let's just -- you can lead me through questions on --
Q. Okay. And it -- it states here in this guidance -- the nonbinding guidance that: An adverse reaction is an undesirable effect reasonably associated with the use of the device that may occur as part of the effect of the device or may be unpredictable in its occurrence."
That -- did I read that correctly?
A. Yes.
And then you have to just go on. Because you may want to deal with the last paragraph. Well, actually, you -- you want to -- you -- you have both paragraphs too.
Q. My -- my question is -- I want you to assume that -- or a device infection satisfies this standard here for when to include an adverse reaction.
Is it your opinion that a medical device manufacturer also has to warn doctors of the symptoms of infection like fever?

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MS. STOKES: Objection. Form. Improper hypothetical.

THE WITNESS: No. I -- I think if you warn of infection, I don't think that has -- I would not think that fever has to be one of the...

BY MR. JESSEE:

Q. Okay. Why is that?

Fever is certainly a symptom of infection, right?

A. Well, the -- if you're warning about -- if you're warning about infection, those things are relevantly synonymous.

Q. And is it doctors know what type -- what in -- what symptoms infection can cause?

MS. STOKES: Objection. Form. Calls for speculation.

THE WITNESS: I -- I -- I -- I think that doctors would know that, if you put infection down, you are talking the infection could be caused by it -- would -- I mean "infection" and "fever" would be synonymous

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here.

BY MR. JESSEE:

Q. And would it be fair to say if -- for adverse events that you're -- that are being warned about that doctors are aware of, you don't have to list every single symptom that an adverse event may actually cause in a patient?

MS. STOKES: Objection. Form. Improper hypothetical. Calls for speculation.

THE WITNESS: Yeah. I -- you're ask -- now you're getting a little vague or -- give me a specific -- I'm not very comfortable answering infection and fever.

BY MR. JESSEE:

Q. Okay. Well, what about --

A. And now we're --

Q. -- infection in -- and redness?

MS. STOKES: Objection. Form. Improper hypothetical.

THE WITNESS: I think, if you had -- I think -- again, whether you have to have

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erythema, if you -- if you -- if you had evidence of a skin infection in a derma -- dermatological infection, you'd probably want to give evidence of dermatological infection if -- if that would be useful to a doctor.

BY MR. JESSEE:

Q. Okay. And you're saying "probably" here.

I mean there's no clear black-and-white rule, right, when it comes to what -- the symptoms you should include at a --

A. What --

Q. -- form adverse events.

MS. STOKES: Objection. Form. Vague.

THE WITNESS: Yeah. I mean it's -- it -- this is not -- this is pretty well agreed to. I don't think this -- this is hard. If you look at -- it is the adverse reaction that -- or the potential safety hazard or the untoward effect, depending on which section we're -- we're dealing with.

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So I think you -- the most important thing is is this information that would be relevant to a doctor, important to the doctor and the patient to know about.

BY MR. JESSEE:

Q. Okay. And --

A. So -- so -- so -- so if, in fact, right, that this caused a change in skin -- this drug caused a change in skin and a redness, and that's something you should be aware of, right, then you'd want to list erythema.

Q. And when you say it's for the -- the physician using the device, in this case it's going to be the hernia mesh -- the surgeon who's using the hernia mesh, right?

A. Well, you'd want -- yes and no. You want to make sure that the -- that -- while the IFU goes toward, in general, the physician, this is also the basis for which the physician and the patient determined informed consent, right?

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So this is information that is useful that the physician has to be -- will use sometimes to -- many times to have a discussion with the patients.

Q. And it's certainly -- we've -- I know you've testified to this numerous times.

It's certainly not the only source of information that physicians use for their informed consent discussions, right?

A. Correct. But --

MS. STOKES: Objection. Form.

THE WITNESS: Correct. But it -- it is -- it's sort of the hub, right? I mean it -- I mean there may be handbooks. There may be other things written that use this. But this is sort of central.

So the question is should you be on the lookout. Is something going to present with redness, and that's something you should be on the lookout for? Is this going to be -- is this a chronic infection? I mean you have to give me the specifics.

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BY MR. JESSEE:

Q. Have you ever drafted an instructions for use?

A. I don't recall. I'm sure I've -- I'm sure I've been involved in labeling and what the label says.

Q. And I'm -- and I -- I'll tell you you've previously testified you've never drafted an instruction for use.

Is that accurate as we sit here today?

A. I --

MS. STOKES: Objection. Form.

THE WITNESS: I -- I -- I mean I -- I would rarely be the person who would sit there and write the whole thing out. I am sure, if you look at the breast implant labels and other things and the IFU and -- as they went out, I'm sure there were discussions that I had input.

BY MR. JESSEE:

Q. Okay. And that would have been,

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when you were at the FDA, you're providing input on the labels?

A. On the IFU. Sure.

Q. The -- have you reviewed the IFUs for any hernia mesh products not made by Bard?

MS. STOKES: Objection. Form.

THE WITNESS: I think some of them are referred -- yes. I'm -- I -- I believe I looked at some of the contraindications for some of the other products, specifically what they said about intraperitoneal use, et cetera, over time.

Q. And what -- what products would that be?

A. I think I probably looked at Gore-Tek -- Gore-Tek had a dual mesh -- and what was said and what were the contraindications. And I think that's in the 510(k) -- again, in the Bard 510(k).

Q. Outside of what the -- in the 510(k)s for predicate devices, have you reviewed any hernia mesh labeling for other

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manufacturers?

A. I mean I --

MS. STOKES: Objection. Form.

THE WITNESS: I think I probably -- I may have looked at some of the I -- I may have typed in some of the IFU language on some of the other devices into Google.

BY MR. JESSEE:

Q. Well, and -- so you may have -- did you -- I mean do you know if you did or not?

A. I have a recollection of having looked at. Because I was interested in what some of the contraindications were.

Q. Okay. And that's the -- your focus of looking at those other labels was, the contraindications?

A. That's just what -- I mean and the -- some of the warnings, yes.

Q. Okay. Well, I don't see any of the other IFUs listed on your long list of materials provided. So I'm just trying to make sure I understand.

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Did you rely on reviewing any other IFUs in coming to your opinions in this case?
A. I -- I -- I --
MS. STOKES: Objection. Form.
THE WITNESS: I relied on what I relied on in my reliance list. I may have seen and I may have searched as I just told you.
BY MR. JESSEE:
Q. Have you reviewed the labels for other medical devices that have an -- a resorption period listed?
MS. STOKES: Objection. Form.
THE WITNESS: I've looked at specifically the -- the resorption studies that I cite are cited in my report. And in statements -- are you asking me if I looked at any documents on complete healing periods and resorption periods?
BY MR. JESSEE:
Q. No.
I'm asking whether you've looked in -- at other IFUs besides the Ventralight --

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besides the Sepramesh that -- to talk about resorption periods in them?
MS. STOKES: Objection. Form.
THE WITNESS: I -- I don't recall sitting here specifically.
BY MR. JESSEE:
Q. Okay. I want to talk something about your opinions on the Ventralight.
A. Ventralight?
Q. Yep.
A. Sure.
Q. And so what I'm going to do now is just -- can you --
A. Can you just do me a favor?
Q. Yeah.
A. Can I just get Ventralight and --
Q. Sure. Do you need a second or --
A. No. I'm -- keep on going.
Q. What I'm -- what I was going to give to you, too, just so you have it in front of you, are the Ventralight IFUs and then the 510(k) that was submitted for the

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Ventralight ST.
A. Sure.
THE WITNESS: Let me just -- let me just give -- if you can give me Ventralight I will trade you, please.
(Discussion held off the stenographic record.)
(Deposition Exhibit 28 was marked for identification.)
(Deposition Exhibit 29 was marked for identification.)
BY MR. JESSEE:
Q. Doctor, I'm going to hand you the IFUs that we've marked as Exhibit 28.
And if you have them before you, that's fine too. I just wanted the make sure --
A. I have the 510(k).
Q. And Exhibit 29, which is the 510(k) for the Ventralex.
And that's something you said you had --

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A. Ventralex or Ventralight?
Q. Excuse me. I misspoke. Ventralight ST.
A. I have portions of the 510(k).
MS. STOKES: And you said 510(k).
MR. JESSEE: No. That's the -- I'm giving you the --
MS. STOKES: Oh, I got you.
THE WITNESS: You're giving me the 510(k).
MS. STOKES: Okay. So IFU is 28.
MR. JESSEE: Yes. And -- let's see.
THE WITNESS: Okay.
BY MR. JESSEE:
Q. And your discussion in your expert report of the -- your opinions regarding the Ventralight ST, it starts on page -- we're on Page 61, I believe. Maybe we can just turn there to orient ourselves.
A. Sure.
MS. STOKES: What page are you on?
MR. JESSEE: 61.

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BY MR. JESSEE:
Q. And this is Section 8 of your report?
A. This is page -- sorry?
Q. 61.
A. Right. Correct. That's the beginning.
Q. And your opinion in this -- I believe what you said earlier is there -- what your focus was on on Ventralight ST was that the Bard statement regarding reabsorption of the hydrogel barrier in the Ventralight ST's IFU is misleading because it could give the surgeons the impression --
A. What paragraph are you reading?
Q. The header --
A. You're at -- thank you.
Q. -- right at the top of the page.
A. Thanks.
Q. Because it could give the surgeons the impression that Ventralight ST's resorbable barrier lasts for 30 days?

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A. Correct.
Q. And you note on here that -- the 510(k), that was cleared by the FDA in July 15th, 2010, correct?
A. Just give me the paragraph number.
Q. Sure. It was on -- Paragraph 170.
A. Thank you, sir.
Q. And we have handed you as an exhibit also the 510(k).
And this is something obviously you've reviewed, correct?
A. I have looked at the 510(k), yes.
Q. And the -- there are instructions for use submitted with the 510(k), correct?
A. Sure.
Q. And that's something that's typically submitted with 510(k)s?
A. Sure.
Q. And always in the case of surgical mesh, correct?
A. Sure.
Q. And there also had the predicate

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devices 510(k) -- excuse me. I'll with -- try that again.
The 510(k) also includes the predicate device Sepramesh IP's IFU as well.
MS. STOKES: Objection. Form.
THE WITNESS: I'm sorry.
BY MR. JESSEE:
Q. Sure.
You want me -- I can give you a Bates number if that would help you find...
A. Sure. We -- we did discuss the definition that usually there are predicates upon predicates.
Q. Okay. And -- well, let's look at the actual 510(k) submission --
A. Sure.
Q. -- here and see what's listed as the predicate device.
Can you agree that it's a requirement that a manufacturer, when it submits a 510(k) must list what the predicate device is, right?

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A. Correct.
Q. And the -- here are listed several of the Sepramesh IP 510(k)s as a predicate device.
A. Can you just give me the page.
MS. STOKES: Objection.
THE WITNESS: There's multiple places where this is.
BY MR. JESSEE:
Q. Okay. And --
A. Just give me the -- there's a page on substantial equivalence and what the predicate is. I just don't have that. We can just get to it.
Q. Sure.
So if you look at -- in -- it's Page 27 in -- of the 510(k). If you look at the Bates number, it ends in 417.
A. I'm there sir.
Q. And this is the 510(k) summary.
That's one of the areas where a manufacturers list the predicate device,

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correct?
A. The immediate predicate. Correct.
Q. Okay. And here we have listed as the predicate device Sepramesh IP bioresorbable coating/permanent mesh. And then there's three different 510(k) numbers listed there, correct?
A. Correct.
Q. And the FDA, in the -- any of the correspondence you've seen, have they suggested that Bard's representation of those three device -- those three 510(k)s as a predicate was inaccurate?
MS. STOKES: Objection. Form.
THE WITNESS: I'm not sure I understand the question.
BY MR. JESSEE:
Q. Have you seen any communication from the FDA stating -- telling Bard that they need to be listing other devices as their predicate?
A. I'm sorry. That's just not the way it works. I -- I'm not sure --
Q. I know. That's my question though.

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I'm just asking if you've seen those communications.
A. No. But --
MS. STOKES: Objection. Form. Assumes facts.
THE WITNESS: Those certainly are not predicate pre1997 devices, sir. But -- this is the immediate predicate that is listed here. You have to be substantially equivalent to a pre1976 device under the act.
So of course there's predicates to the predicate to the predicate, right? So all this is asking is what the -- you know, what the immediate predicate is. This is not listing all the predicates. Because these predicates are based on other predicates.
BY MR. JESSEE:
Q. And can you point me to a specific FDA regulation that talks about the predicate chain that you've been referring to?
MS. STOKES: Objection. Form.
THE WITNESS: Just go to the

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statute.
BY MR. JESSEE:
Q. Okay. What -- what version -- what section of the statue --
A. This --
Q. -- says predicate chain?
A. Well, the -- the statute says you have to be substantially equivalent to a device that was on the market prior to 1976.
Q. Okay. And what -- what statutory provision are you referring to?
A. I -- you have to look at the substantial equivalent. But it's always to a device that was preamendment. So you're -- you're the same as something that was on the market pre-'76. So there's always a predicate chain.
It's a -- it's -- it's -- it's FDA 101 that -- I mean you're -- you're just not substantially -- you have to -- when the acts -- when the act got passed you have -- in '76, and as the 1990 Act reflected, was as long as

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you're the same as and don't raise new questions compared to something that was on the market was grandfathered, you could get on the market.
But the -- but the whole history of this is I'm the same as something that's I'm the same as that I'm the same as. That's what's gone on with substantial equivalence.
Q. Can you point me -- and my question -- and I'm trying to be -- it's getting -- I know -- late in the day.
I'm just -- I'm trying to just get very simple -- can you point me to a regulation that says -- FDA regulation that uses the term "predicate chain"?
A. I don't know if it's in a regulation. But it's in -- I mean I've written probably articles that talk about substantial equivalence.
And the -- go to any basic medical device law introduction to 510(k), and substantial equivalence is based on predicates

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that have to go -- you have to go back to pre-'76. And you have to show you're the same -- you don't raise any new safety questions to that original device.
That's the whole premise. That's the whole congressional premise.
Q. Did you -- you can agree -- we can agree that the Ventralight Sepramesh labeling was included in this 510(k)?
A. The IFU?
Q. The IFUs, yes.
A. Sure. The --
Q. And the -- and specifically the language that you take issue with was included in these 510(k)s that were submitted to -- to the FDA, right?
MS. STOKES: Objection. Form.
THE WITNESS: So -- so tell me what the language is that I -- so -- so we can --
BY MR. JESSEE:
Q. Sure.
Looking on Page 54 of the 510(k).

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A. Okay. And keep on going. Show me where, please.
Q. The -- "Shortly after placement of the biopolymer coating in this limited description."
A. Just show me where -- where we are after -- i description?
Q. Yeah. The very bottom last sentence.
A. Right. The bottom last sentence.
Q. And that's -- that -- you can correct me if I'm wrong, but I believe that's the statement that you take issue with; is that accurate?
A. Well, it -- it --
MS. STOKES: Objection. Form.
THE WITNESS: It is -- that is the -- the statement, in part. But I also take issue with the fact that the claim as discussed here talks about that -- that it lasts for the complete healing period.
BY MR. JESSEE:

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Q. Okay. And where is that in the IFU?
A. That's -- that's in the -- that's in promotional materials, I believe.
Q. Right. That's a separate -- I'm talking about the IFU opinions though, the -- this is the sentence that you take issue with, correct?
MS. STOKES: Objection. Form.
THE WITNESS: I take issue with a number of the claims.
BY MR. JESSEE:
Q. Okay. And you didn't -- what -- you didn't, in your report, address any other issue, any other criticisms, or any other part of the -- the -- the IFU except for this one sentence.
A. I -- I would have to go back exactly. But I certainly -- any sentence that this lasts for the complete healing period, that's what I would take issue with.
Q. Okay. What's the -- in your mind, the complete healing period?

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A. I mean as -- you know, the -- if you look at -- in Bard's own -- let me just give you a Bates number, if I have it. I may not have it. May -- I don't have a Bates number. I have a native document.
If you look at a Bard's document, as of July 16, 2015, from Debbie Tripodi to Justin Piza, and they -- and the subject is "Critical Healing Period."
According to Bard it says that the typical critical healing period is four weeks. And it gives two cites, one to a textbook and one to FDA meeting minutes.
And the FDA, in meeting minutes with Bard on -- in a document that I'm happy to give you, that is actually cited here and is part of this attachment, says JN, who is one of the FDA officials stated eight weeks is too long; four to five weeks is preferable as the critical healing period.
So one -- so Bard's conclusion is the critical healing period is four weeks.

Q. Okay. And when you say Bard's conclusion though, you're talking about a specific person who's a specific employee?

MS. STOKES: Objection. Form.

BY MR. JESSEE:

Q. And -- and can you read me the -- since I don't have these in front of me, what you're referring to?

A. This -- this -- your database only prints out the native. I couldn't -- I tried to print out a --

Q. Okay. Well, it's not our -- it's not my database.

A. No, no, no. Your -- you -- the way you -- sorry.

Q. Well, I mean I'm able to --

A. Your -- your -- your client produced this --

Q. Okay. We --

A. -- in the native. You can just take a picture of this. This is -- this is -- this is the native document.

Q. Can you just give me the date of it?

A. Sure. On July 16, 2015.

Q. Okay. And who is the document from?

A. Debbie, T-R-I-P-O-D-I.

Q. Okay. And do you know what position she has at -- at Bard?

A. She's a senior product manager.

Q. The -- is it -- would it be accurate that, if there is scientific evidence that the barrier -- the hydrated gel is resorbed in 30 days, then the -- that statement is not misleading.

MS. STOKES: Objection. Form.

THE WITNESS: I looked at the studies, I mean one by one, and looked myself at -- at the studies. And I certainly didn't see evidence that the ST layer stayed that -- that 30 days.

BY MR. JESSEE:

Q. And respectfully though that wasn't my question.

My question was, if there is

evidence out there that shows that the barrier lasts for 30 days, that statement's not misleading.

We can agree on that, right?

MS. STOKES: Objection. Form.

THE WITNESS: Are you living in an alternate reality world?

BY MR. JESSEE:

Q. I'm -- can you answer the -- the question?

If there is evidence -- how can -- is that statement misleading?

Because that's -- your criticism is there's not evidence to -- that it support for 30 days.

If there is evidence --

A. I'm --

MS. STOKES: Objection. Form.

THE WITNESS: What I'm saying is, if it gives the impression that it let -- that it's okay to use this in the intraperitoneal space because this layer is around long enough

and lasts longer than the healing period -- the -- the healing is done, right, while the layer is still there, it would be misleading. That's my concern.

I mean you can have scientists talk about the resorption period. I can tell you I've looked at -- other scientists can also add. I've looked just what the studies show and I don't see this layer -- the evidence of this layer lasting 30 days.

BY MR. JESSEE:

Q. And you haven't done testing yourself on it though.

Can we agree on that?

A. I -- I'm -- I -- that's correct. But I have looked at every single one of Bard and Genzyme's studies and have cited them.

Q. And how many of those study that you cited to involved the Ventralight ST?

THE WITNESS: So can I have my Ventralight.

BY MR. JESSEE:

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Q. And would you mind just -- what -- what -- the one you have been looking at, what's the exhibit number?
MS. STOKES: 12, I think.
THE WITNESS: 12, sir.
MR. JESSEE: 12. Okay.
THE WITNESS: So we can --
BY MR. JESSEE:
Q. And -- and, Doctor, before we do that, I still haven't gotten --
A. You're -- you're -- you're asking a lot of questions. Let's stay with one question at a time.
Q. I know. I still haven't got my one question answered though --
A. Okay.
Q. -- is the problem though.
If -- if the -- there is scientific evidence showing that the coating, when it becomes a hydrated gel, is absorbed in 30 days, is this statement "shortly after placement, the biopolymer coating becomes a hydrated gel that

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is resorbed from the site in less than 30 days," is that misleading?
MS. STOKES: Objection. Form.
THE WITNESS: If you -- if your studies showed -- I mean let me make sure I understand this. If your study showed that this coating lasted throughout, then obviously -- I mean until complete healing, then that would not be misleading if there were studies that showed you lasted throughout that complete healing period.
BY MR. JESSEE:
Q. And it doesn't though here in this -- I -- if you say "complete healing period."
A. What I mean --
Q. It says 30 days?
A. Well, but that's the -- the -- the -- the concern --
Q. And would you agree --
A. Just -- just one second.
Q. Yeah. Sorry. I didn't mean to interrupt you.

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A. Just -- okay. I got to -- the -- just -- just hold on one second.
If, in fact, this -- well, I mean as -- as -- as Bard's employees say, by saying that it lasts up to 30 days, right, and if it, in fact, only lasts seven days, that may compromise what the surgeons' opinions of how effective the barrier is.
So surgeons I mean want to make sure that this barrier is there and is going to -- if you're going to -- if you're going to the use this in the intraperitoneal space, you got to make sure that it's going to protect against those -- those adhesions and those other consequences of mesh attaching to bowel until that healing period. That's what surgeons want.
Q. Have -- have you spoken with any surgeons about the Ventralight ST?
A. No. No. But I've read what Bard's view of what the surgeons want.
Q. Okay. But you haven't spoken to

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them about the resorbable barrier, any surgeons?
A. No. But -- but it -- but it -- it's clear from Bard's own sales force that, if you -- if the barrier only lasted seven days, that that was too short, and you needed -- and surgeons want to make sure that it can safely put.
But the whole question is how could this possibly be substantially equivalent when these questions are not answered? Why are we putting this -- saying this is the same as these other devices going all back the predicate chain when there's all this controversy on how long this lists, and that's not been determined?
Q. Do you know how -- how long Sepramesh has been on the market, Sepramesh IP -- IP?
MS. STOKES: Objection. Form.
THE WITNESS: So I -- I'd have to look that -- I have the -- the 510(k). I can

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look that date up.
BY MR. JESSEE:
Q. Do you know how much --
A. But -- but -- please. The issue is not Sepramesh. The issue is how long will Sepramesh, once it's attached to the polypropylene, right -- the issue is isn't the -- the Sepramesh and the Genzyme. It's whether it will protect the -- the polypropylene. And that's the key -- key question.
Q. Well, and the -- no the key question is how is -- if -- if it's -- how it's impacting -- how it's working in -- in patients, isn't it?
A. Right. And that's --
MS. STOKES: Objection. Form. Argumentative.
THE WITNESS: -- why you do human trials before you experiment and do -- on -- using humans as guinea pigs.
BY MR. JESSEE:

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Q. And right.
And how -- what are the -- what are clinical studies on the Sepramesh and the Ventralight ST, the numerous clinical studies, what do they say about that?
A. I --
MS. STOKES: Objection. Form. Argumentative.
THE WITNESS: And -- and I can tell you, okay, that you don't have those human studies that answer that question --
MR. JESSEE: Okay. The --
THE WITNESS: -- as part of the -- as part of the 510(k).
BY MR. JESSEE:
Q. And I'm not talking about the 510(k) right now.
A. But that's --
Q. I'm talking about 2020 in -- for this device that's used at the University of California San Francisco on a regular basis, the -- as I say you're -- are you offering the

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opinion that there is not, at this point in time, clinical evidence of this device?
MS. STOKES: Objection. Form. Argumentative.
THE WITNESS: You've not established the safety and effectiveness of the --
BY MR. JESSEE:
Q. No. I'm asking you.
Are you offering that opinion that's it's unsafe?
A. My -- my --
MS. STOKES: Are you going to let him finish?
THE WITNESS: My opinion is that, if you look at what Bard submitted to the agency, you've not established safety and effectiveness. You've established that it was substantially equivalent to Sepramesh, which -- which was going back to Composix mesh, which was the same as Gore-Tex. You've never established safety and effectiveness. And you should have done human clinical trials.

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BY MR. JESSEE:
Q. So in the -- in the -- my answer to my question, you can't say whether today the medical literature out there, the clinical studies that have been done, establishes whether it's safe or not, Ventralight?
MS. STOKES: Objection. Form. Vague.
THE WITNESS: You -- you -- your company did not establish that.
BY MR. JESSEE:
Q. Not my question, Doctor.
A. Your company did not establish safety and effectiveness of this device and never under -- never undertook that.
Q. Doctor, that -- I think -- come on now. You understand what my question is here.
A. So --
Q. Are you offering an opinion one way or the other --
A. I'm -- I'm --
Q. -- on the clinical literature out

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there on Ventralight and Sepramesh?
MS. STOKES: Objection. Form.
THE WITNESS: The -- the -- the general view and the consensus statements of the -- certainly the European Hernia Society is -- is that, if you're going to use these kind of meshes, you should use them -- if you're going to -- if you're going to use mesh in these ventral hernias, you do it pari-peritoneal, and you're careful about not putting these in intraabdominally.
There is not safety and effectiveness that is accepted about intraperitoneal use of Ventralight or any of these composites. That safety and effectiveness has not been established. That's why the consensus studies that has those opinions are moving toward preperitoneal use.
MR. JESSEE: Let -- let's -- let's take a break.
THE VIDEOGRAPHER: We are going off the record. This is the end of Media Unit No.

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4.
The time is 6:01 -- I mean -- sorry. Time is 3:27.
(A short recess was taken.)
THE VIDEOGRAPHER: We are going back on the record. This is the start of Media Unit No. 5.
The time is 3:43.
BY MR. JESSEE:
Q. Doctor, do you know what the America's Hernia Society quality collaborative is?
A. I did I read -- there were some statements about certain -- in the record about that.
Q. And what's your understanding of what that is?
A. It was a group that -- I'd have to -- I'd have to review to be exactly certain. But it was -- the context was getting certain data with Bard, as I -- as I understood it, at a certain point in time.

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Q. Do you have an understanding of whether it's just with Bard or with other manufacturers?
A. I think it's with other manufacturers.
Q. Do you know that the FDA has access to that data?
MS. STOKES: Objection. Form.
THE WITNESS: I'm not sure I'm aware of that. I just don't -- don't recall.
BY MR. JESSEE:
Q. Okay. So you don't know one way or the other whether the FDA has access to the AHS QC data?
A. No. I didn't study that.
Q. The -- turning back to the Ventralight ST.
Do you know how many times the FDA has reviewed the statement about resorption within 30 days?
MS. STOKES: Objection. Form. Calls for speculation.

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THE WITNESS: How many times the 510(k) has been looked at. I can tell you -- I mean I -- I -- I think there's two Ventralight 510(k)s, if I -- but I -- I don't know specifically. I don't have a record of -- of how many times FDA has looked at that --
BY MR. JESSEE:
Q. Do you know --
A. -- specific --
Q. -- how many time -- how many Ventralight 510(k)s there are?
A. So -- just give me one second.
Q. And can you tell me what you're -- I'm not -- can you tell me what you're looking at right now, please.
A. I'm looking at -- I'm looking at my own index of all the 510(k)s that I have pulled.
Q. Okay. Is this -- so is this separate from the documents that you -- hard copy documents you brought with you today?
A. Yes.

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Q. All right. And can we get a copy of that index?
A. Well, so here it is. Here -- they're just PDFs into a folder of --
Q. And --
A. -- 5 -- 510(k)s.
Can you -- let me just answer one question --
Q. Sure.
A. -- at a time, if I can.
Just give me one second.
Q. And, Doctor, I just -- respectfully, we can go off the record if you want to spend time looking through this, but --
A. But I -- I have -- I -- I have put various 510(k)s in here under Ventralight. Hold on a second. And I'm happy to -- you know, whenever you -- just give me one second.
I -- I don't want the take your time. But I do have -- and I -- for some reason I thought there were at least two K numbers. But I -- I'd have to pull them up.

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Q. Okay. Have you reviewed every 510(k) for Ventralight?
A. I have tried to view -- I can -- I will tell you exactly what I reviewed when -- I just missed it for some reason. Here it is. I'm sorry. Here.
So what I have is -- here it is. I think this is -- so I have reviewed two Ventralight 510(k)s. One -- actually, they're both the same K number. So I have reviewed -- sorry -- K101851.
Q. Okay. And have you reviewed the Sepramesh 510(k)s?
MS. STOKES: Objection. Form.
THE WITNESS: So I have viewed -- sorry. This is -- I have viewed --
MS. STOKES: You're touching your mouse.
BY MR. JESSEE:
Q. And is what you're looking at a -- it's your list of the 510(k)s you've actually reviewed and --

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A. No. It's actually the 510(k)s themselves here.
So I have -- but my computer for some reason is going kablooey. Here it is.
So I have Sepramesh. I have the K053066. I have that. That's Sepramesh that I've looked at at one point in time. That's the -- and I have an -- a Sepramesh K40868 also.
Q. Have you reviewed the FDA review memorandum for any of the Ventralight or Sepramesh?
A. Yeah. So I have the FOI documents for Sepramesh.
Q. Do you know whether Bard has ever discussed the resorption rate or testing on resorption with FDA?
A. I -- I --
MS. STOKES: Objection. Form.
THE WITNESS: I'd want to review that. I don't have a --
BY MR. JESSEE:

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Q. You don't have it as we sit here right now with you?
A. I don't have that in -- it certainly has -- I don't -- I don't know that specifically.
Q. Okay. And that's fine.
Let's -- with the -- you'd agree that there was -- in the 510(k) for the Ventralight, Bard talked about an animal testing that it had done, right?
MS. STOKES: Objection. Form.
THE WITNESS: So -- hang on a second.
So I have -- I mean it talked about -- in the 510(k) on Ventralight, it talked about the biocompatibility testing. I certainly have all the -- the biocompatibility testing.
BY MR. JESSEE:
Q. And did you review -- and the -- there's also preclinical testing discussed in the -- in vivo preclinical testing four-week

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implant in a pig discussed in the 510(k), correct?
A. So I have -- I have the subchronic 13-week in rats --
Q. Okay.
A. Here.
Q. Do you know what --
A. Hold on a second. Let me just get -- so I am aware of -- there are several -- I think there are -- one, two -- one two, three, four, five -- five -- well, some are Ventra -- Ventralight. I'm sorry.
There's a Ventralight pig study -- a porcine study with ten pigs that I'm aware of.
Q. And what's the exhibit number you're looking at, the sticker for this page?
A. 15.
MR. JESSEE: Okay. Let's quickly mark exhibit --
BY MR. JESSEE:
Q. What -- while we're looking for that, the -- what's the -- in your opinion, the

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clinical significance if the resorbable gel does not last for the 30 days?
MS. STOKES: Objection. Form.
THE WITNESS: The -- the issue is you can't -- you can't put mesh -- you're not going to put polypropylene mesh into the bowel unless you can protect the consequences of that mesh.
BY MR. JESSEE:
Q. Right.
And so my question is what is the clinical consequences?
A. Right.
MS. STOKES: Objection.
THE WITNESS: So the -- the -- you can end up with mesh in the bowel, right?
BY MR. JESSEE:
Q. Do you know what the rate -- and that's commonly known as adhesion?
A. Well, be -- be a little careful. There's adheres. There's intrusion. There's obstruction. There's a number of different

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words.
But I mean there's -- I mean the -- the real issue is -- I mean the things -- the downstream consequences of obstruction and can -- and the mesh ends up in the bowel.
Q. Do you know what the reported rate in literature of the Ventralight of any kind of mesh getting into the bowel -- any of the issues you just described are?
A. I'm not --
MS. STOKES: Objection. Form.
THE WITNESS: I -- I -- I have not -- we talked about reporting rates.
BY MR. JESSEE:
Q. In literature, I'm talking about.
A. I have not -- I do not have those data.
Q. Okay.
A. You can ask the surgeons that.
Q. Okay. I'm going to go ahead and just show you -- ask you have a few questions about two documents. Here you go.

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And this is just one of the studies that I think you cite to in your schedule, and it's one you've seen before, right?
A. Yeah. I have to just get oriented and see which study you're referring to.
(Deposition Exhibit 30 was marked for identification.)
BY MR. JESSEE:
Q. And this was actually submitted with the Ventralex ST 510(k), as you can see?
A. Yeah. I'm not questioning -- I don't question that.
So this is Davol -- what's the report number -- ending in 35 -- 357. Hold on a second. So this is not -- some of these have multiple different numbers an DB numbers. Hold on one second.
MR. JESSEE: All right. Let's go off the record, please.
THE VIDEOGRAPHER: We are going off the record.
THE WITNESS: What -- what -- what's

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your question?
MR. JESSEE: That's fine. Why don't you take a minute and look at --
THE VIDEOGRAPHER: We are going off the record.
The time is 3:53.
(A short recess was taken.)
THE VIDEOGRAPHER: We are going back on the record.
The time is 3:54.
BY MR. JESSEE:
Q. Doctor, in the first page of the document I handed you, you can see at the bottom that this is part of the 510(k) submission for the Ventralight -- or Ventralex ST. Excuse me.
A. That's what it says, yes.
Q. Did you review the 510(k)s for other devices -- for the Ventralex ST?
A. So this -- I'm sorry. I have the Ventralex, as I just said. I have the 510(k).
Q. Okay. For the ST as well?

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And you understand --
A. Yeah.
Q. -- there's a difference between the Ventralex and Ventralex ST?
A. I'm sorry. You -- you -- you just now switched on me from Ventralight -- I apologize.
Q. Yeah.
A. You went -- you went from Ventralight. You're now -- you're now going to Ventralex. I'm sorry. I thought we were still dealing -- that's why I couldn't find this under my Ventralight.
This is -- you're -- this is from Ventralex --
Q. Yeah.
A. -- 510(k). Okay.
Q. Ventralex ST.
THE WITNESS: Keep on going.
Just -- just bring me my 510 -- my 510 -- my Ventralex studies.
BY MR. JESSEE:

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Q. So, Doctor, if you could turn to Page 850 of this or the -- the Bates --
A. And this is -- this is not on Ventralex or on Ventralight, correct?
This is Ventrio.
Q. This is -- and if you look at the -- the device that's actually at issue here, it's Sepramesh IP and Ventrio.
A. It's Ventri -- so it's not -- we're not talking about Ventralex or Ventralight.
Q. Yeah. We're talking about Sepramesh IP.
A. This is --
Q. The one that you said is substantially equivalent to Ventralex?
MS. STOKES: I think we're very confused here. So this is a submission for Ventralex ST?
MR. JESSEE: Yeah. It -- that's what I was pointing out right at the bottom.
THE WITNESS: Right. But it's -- but it's -- but the -- but the device that's

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being tested is not Sepramesh, as you just told me.
BY MR. JESSEE:
Q. The -- all right. We'll -- we'll get there.
A. The device on Page -- I mean --
Q. If you look at --
A. -- 834 says this is Ventrio ST.
Q. That's what the report says.
If you go to 838.
MS. STOKES: I'm sorry. What page now?
MR. JESSEE: It's 838, Bates No. 988.
THE WITNESS: I -- I see that.
BY MR. JESSEE:
Q. Okay. And you see the different test controls, one being S -- Sepramesh IP?
A. I -- I -- I see that.
Q. Okay. If you could turn to Page 850, Doctor.
A. Correct.

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Q. This is "Histopathology Summary."
Do you see that?
Are you on that page?
A. Let me just see. So this is Sepramesh. Correct.
Q. And if you look about halfway down, there's a sentence that starts "However."
You see where I've started there, "However a reduction in distance"?
A. Right.
Q. It says: "However a reduction in distance between the polypropylene fibers and the visceral surface of each device is consistent with absorption of the hydrogel barrier by 28 days."
Did I read that correctly?
A. That's what this says.
Q. If you could turn to Page 890.
And this is a report by DaVinci Biomedical, right? Correct?
A. That's what this said -- that's what the heading is.

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Q. And if you would read at the very -- the last sentence of this conclusion, it starts -- the what sentence, it breaks into the next page.
It says: "Furthermore a reduction" --
A. Wait. Wait a second. Just --
Q. Sure.
A. You're very good. But you just need to point better where --
Q. Yeah. Last sentence of the page where it goes into the next page --
A. Right.
Q. -- is what I was trying to get at.
"Furthermore, a reduction in distance between the polypropylene fibers and visceral surface of Ventrio ST hernia patch and Sepramesh IP composite by 28 days is consistent with absorption of the hydrogel barrier."
Did I read that correctly?
A. You did.
Q. The are you aware of any preclinical published studies by people outside of Bard looking at the absorption period for Ventralight and Sepramesh?

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A. I cite this -- I cite -- yes. There were Genzyme studies.
Q. And I -- I should clarify. Outside of Bard or -- or Genzyme. I'm talking about in published -- published scientific literature?
MS. STOKES: Objection. Form.
THE WITNESS: No. I'm -- I -- I'm not sitting here -- I mean I'm -- I'm aware of what was in the record by the --
BY MR. JESSEE:
Q. Okay. The -- on Page 75 of your report -- we're switching tracks now to the large Ventralex and your opinions on that.
A. Okay.
Q. Page 57 of your report, you talk about that -- Paragraph 208.
A. Yes, sir.
Q. And it's your been -- been your practice, both at FDA and afterwards, to rely on engineers to evaluate the adequacy of mechanical as opposed to clinical design characteristics of devices and to evaluate the proper design control processes for assuring proper performance of these devices.

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A. Correct.
Q. And with regard to this issue of ring buckling.
And that's a mechanical, not clinical issue, right?
MS. STOKES: Objection. Form.
THE WITNESS: Not -- not entirely. That -- that would be incorrect. As you -- your medical director, Dr. Ciavarella, has testified, that obviously is a clinical -- that -- that has -- there's mechanical components of that. But ultimately, I mean he's the one who said that -- I think I cite him -- recommended that additional testing -- long-term testing be done.
So it's -- it's the medical director. And I think the -- the key aspect of

some of the -- so it's not just mechanical, is the answer to your question.

BY MR. JESSEE:

Q. Okay. But you rely on a -- an engineer for several opinions in this section, do you not?

MS. STOKES: Objection. Form.

THE WITNESS: I -- I think that I -- I think, if -- if you add the word "in part," okay, I do cite that. But I mean there's also the clinical aspects. Ciavarella's not a mechanical engineer. He's -- he's a -- a medical director. And he -- it's -- it's -- I mean, as he would -- I don't need a mechanical engineer to basically agree with Ciavarella.

BY MR. JESSEE:

Q. As a -- as we sit here without looking into the documents, do you recall whether any surgeons at the FDA provided input on the labeling for the Ventralex device?

MS. STOKES: Objection. Form.

THE WITNESS: I'd have to pull the

Ventralex 510(k) correspondence on that to --

BY MR. JESSEE:

Q. The --

A. -- answer that question.

Q. It says here you requested counsel to engage quality system engineer John Quick?

A. I did. Well, I -- I -- I -- I asked them to have somebody look at the QSM aspects at Bard at -- at Bard as it relates to this device.

Q. Okay. And there's not -- so there wasn't -- you didn't specifically ask for Mr. Quick then?

A. I don't believe at any point that I -- I used -- I didn't know Mr. Quick before. I think it would -- I -- I think my request was to have a quality system expert.

Q. Did you talk with him at all on the phone?

A. I'm blocking. I apologize. I just -- it's getting late. I -- and so it's -- it's not that late, but I -- it's late in the

deposition. So I -- I just -- I'd have to refresh my memory. I -- I don't know if I did.

Q. Do you keep notes of any conversations you would have had with other people?

A. I don't recall any. I mean I brought everything -- I -- I don't have any notes with me. And I would have had notes if -- if I had kept -- I just don't recall. I'd have to refresh my memory.

Q. Would -- is there any other expert that you talked to in relation to this case?

A. No.

Q. So it's possible you don't know from --

A. I just don't remember -- I -- I'm just sitting here --

Q. That's fine.

A. -- right -- I'm --

Q. I -- that's fine.

A. I just --

Q. You --

A. There's no -- I just -- I'd have to just refresh.

Q. And you expected Mr. Quick to be qualified in quality systems to assess the quality systems, right?

MS. STOKES: Objection. Form.

THE WITNESS: Yeah. He -- he had run Baxter quality systems for decades, et cetera.

BY MR. JESSEE:

Q. And you were relying on his opinions here that you cite these bullet point to be accurate, correct?

MS. STOKES: Objection. Form.

THE WITNESS: Well, I -- I -- I certainly -- I -- I cite these. But he cites Ciavarella. I don't -- I mean there's certain things that I don't need Quick. I mean I do that for comp -- for the comp -- to be comprehensive. I don't need Quick to cite Ciavarella. I can cite Ciavarella. I can talk about the clinical aspects. So there's a

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little bit of redundancy there.
Q. Do you know what the -- in the clinical literature, what the -- have you seen, in clinical literature on the Ventralex, reports of buckling?
MS. STOKES: Objection. Form.
THE WITNESS: I certainly have seen in the Composix Kugel, et cetera, that history of buckling being associated with the well. But I -- I can't place it exactly sitting here where I've seen -- referred to as different terms by different -- buckling of kinking.
I'd have to go back and re -- remind myself exactly whether I saw it specifically on Ventralex large or whether I saw it on Composix Kugel.
BY MR. JESSEE:
Q. Would it be fair that, to the extent you did see the instances, whether in complaints or in the materials you reviewed, of buckling in Ventralex large, it would be -- you would -- be addressed in your report?

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A. I think --
MS. STOKES: Objection. Form.
THE WITNESS: I do cite complaints here on Ventralex large, I believe on buckling, et cetera. And --
BY MR. JESSEE:
Q. And what page are you looking at?
A. I believe there's -- let's just get this. There are complaints, if my -- my memory serves me right. Unless my memory is off.
So I'd -- I'd have to go back -- I -- I see specifically where -- I -- I have a recollection of certain spreadsheets on complaints. Bard received complaints of ring buckling with the Composix Kugel and the reduced diameter ring.
I certainly -- I think some of those on that spreadsheet also had the word Ventralex. But I'd have to pull those spreadsheets.
Q. Okay. So you don't know for sure as we sit here right now?

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A. I mean I -- I think -- I mean -- no. I'd want -- I'd want to check it -- there's a list of all the complaints and which ones -- but I think some of them overlap with the -- on the -- if -- if I remember certain of the complaint records, they were issues with Ventralex large as well as Composix Kugel. But I need time to pull up those spreadsheets.
Q. Can you tell me what the difference between the ring and the Composix Kugel large and the Ventralex large is?
A. So there was a shift --
MS. STOKES: Objection. Form.
THE WITNESS: So there was a shift -- at what point in time?
BY MR. JESSEE:
Q. In the time you're critical of the large Ventralex.
A. So -- so --
MS. STOKES: Objection. Form.
THE WITNESS: So there was a shift from, what, .0 -- 0.042 to .030?

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Is that what you're referring to?
BY MR. JESSEE:
Q. I'm just asking you about your knowledge.
A. Yeah. So there was a shift in redesign in -- as far as diameter of the mesh from point -- 0.042 to .030.
THE WITNESS: Can I just have my Ventralex sheets.
BY MR. JESSEE:
Q. Do you -- have you reviewed Bard's interactions with the FDA related to the Composix Kugel recall?
A. There's certainly -- yes. I mean there's -- there's numerous ones. I've looked at the 483s. I've looked at the warning letters. I have studied that.
Q. Okay. And with respect to the 483s -- and that -- that's something that's fairly common in medical devices -- in medical -- for the medical device manufacturers that, after an FDA inspection, they'll issue 483s?

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MS. STOKES: Objection. Form.
THE WITNESS: Yeah. I'm not going to -- yes. I'm not going to -- 483 is not going to -- 483s happen. And they -- there -- there's no question. And -- in and of themselves.
Depends what it the 483 is about. I mean is it a 483 about a recall about devices failing? What's the hazard of the device? 438 alone is not going to -- you know, I'm not going to criticize somebody for getting a 438.
BY MR. JESSEE:
Q. Okay. Because like Immucor has gotten 438s, correct?
A. Exactly.
Q. And even in the last couple years, correct?
MS. STOKES: Objection. Form.
THE WITNESS: I'm sure we've gotten 438s.
BY MR. JESSEE:
Q. And again, that's not a -- the 438s

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aren't an official FDA position that the -- there's some kind of safety issue with the device or anything, right?
MS. STOKES: Objection. Form.
THE WITNESS: The recall starts telling you -- I mean, when you start recalling, that's when you start getting into those issues.
MR. JESSEE: Right.
THE WITNESS: The -- the -- the 483s have to do more here with, you know, the -- what the quality system was in place for these devices and whether the quality system -- the quality systems -- the QSMs -- the quality management system -- sorry -- was -- allowed these devices to make sure to minimize and -- the hazards and -- and what should have been done as the design controls when the company shifted to the point -- from the 0.042 to the 0.030 and should that have been tested be -- I mean -- and -- in the long-term animal studies.
And that's what Ciavarella is -- is

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-- is saying. And I mean it's part of the risk management and the quality assurance.
BY MR. JESSEE:
Q. So you're of the opinion the 483 is related to the -- the -- this testing, you're saying?
A. If you don't define --
MS. STOKES: Objection. Form.
THE WITNESS: If you don't define -- the -- the -- the 483s as a whole, if you look at them and talk about the identification of user needs -- user needs or safety. And the question is whether there is adequate design controls to assure user needs and safety issues.
And that was what the FDA was saying. And there was not obviously the adequate testing of the -- these vent -- I mean in the case of Ventralex before that shift was made.
BY MR. JESSEE:
Q. Do you know how many meetings FDA

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had with Bard following the CK recall to discuss their other ring products?
MS. STOKES: Objection. Form.
THE WITNESS: I have -- I mean I -- I have looked specifically, you know, and I've studied, and, you know, I have the slide decks and the -- the presentations that were made if you want to --
MR. JESSEE: Yeah. Let's mark that as an exhibit.
THE WITNESS: I tried to find the meeting minutes from these. And I couldn't find the meeting minutes. So I don't have a -- I may not have a full record. But I have tried to --
MR. JESSEE: Okay.
THE WITNESS: -- study this.
MR. JESSEE: We'll put that as Exhibit -- I believe we're on 30 now.
THE REPORTER: 31.
MR. JESSEE: 31. Thank you.
(Deposition Exhibit 31 was marked

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for identification.)
BY MR. JESSEE:
Q. And, Doctor, have you -- let me strike that.
The -- with respect to the Ventralex large, FDA hasn't taken any enforcement action, correct?
MS. STOKES: Objection. Form.
THE WITNESS: What do you consider enforcement action?
Sorry. Do you consider a warning letter --
BY MR. JESSEE:
Q. Sure. We can include warning letters in there.
A. So the -- the warning letter -- we have to probably -- and -- and there's actually two warning letters, if I think my memory serves me right. There was one in New England, and there was one in Puerto Rico.
I have to look -- I think -- the -- the way I read certain portions of those

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warning letters, they weren't -- they -- they related to the quality assurance system across the board. They were not just specific to one device.
But we'd have to pull those -- those -- that language --
Q. Okay.
A. -- to read. But I -- I think they -- I think they related across the board.
Q. They -- the warning letter is not discussed in your report, correct?
A. The 483s are -- I think they're on my reliance list.
THE WITNESS: Can I get my general --
BY MR. JESSEE:
Q. And -- and I'm talking about the body of your report. The -- I'm talking about the warning letter.
A. The 483 is the warning letters. I think they're --
Q. Well, it --

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A. I think they're on the reliance list.
Q. Okay. And I understand that.
The -- there's a difference between a 438 and a warning letter?
A. Absolutely, sir.
Q. Okay. I jus5t want to make sure we're -- we're clear here.
A. The -- let me just --
Q. And has any Immucor, the company that you're the head of comp -- that you're on the compliance committee for, gotten a warning letter before?
A. I'm sure --
MS. STOKES: Objection. Form.
THE WITNESS: I'd have to go back and look at the history. But there were certainly things that needed to be cleaned up in that company. So I would -- yeah. Again, I would not be surprised. But I have to review the record.
BY MR. JESSEE:

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Q. Have you reviewed the records for Bard as to the actions that were taken after any of the -- the warning letter you referred, the 483s, or any of the external audits?
A. Yes.
MS. STOKES: Objection. Form.
THE WITNESS: I did, sir.
BY MR. JESSEE:
Q. Okay. And are you critical the -- of the actions that Bard took in -- in response to the different feedback that they received?
MS. STOKES: Objection. Form.
THE WITNESS: Well, I mean you have the warning letter, I think, in, what, '07. And then you have, if I'm correct -- can I just have my audit -- my Quintiles audit sheets.
BY MR. JESSEE:
Q. And did you -- is -- did you know --
A. Just -- just -- just let -- I apologize. I'm only as good -- I just need one second to be able to answer your question. I just can't keep more than one question in my

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head.
So if -- if I understand the record, that post Quintile -- post warning letters, there was mock FDA inspection again in '08 and that there is still criticism that some -- there's -- there's issues with the quality system post. And that -- that's shown in the -- in the -- in the mock FDA --
Q. And did you know that Quintiles is owned by TPG Capital?
MS. STOKES: Objection. Form.
THE WITNESS: I'm -- I may have known that. I mean, again, I -- it has been different -- Quintiles is now what? I mean I -- I've -- I have not been involved in Quintiles and TPG Capital. But I have made no -- that -- but I've not been involved in that.
BY MR. JESSEE:
Q. And you know that, from your experience working with Immucor, that when the FDA issues a 483 or a warning letter, that they're going to follow up and make sure issues

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are addressed?
MS. STOKES: Objection. Form.
THE WITNESS: Yeah.
MS. STOKES: Assumes facts.
BY MR. JESSEE:
Q. And have you seen the closeout letter from the FDA for the warning letter at issue for the -- in connection with the Composix Kugel recall?
A. Yeah. So I -- I've specifically -- yes. I have looked -- well, I have -- it's -- it's not labeled as closeout letter. I -- I'm aware of a December 17, 2008 letter.
Is that what we're referring to?
Q. I'm -- have you reviewed what you -- a closeout letter to it?
I'm -- that's all I'm asking.
A. So I -- I --
MS. STOKES: Objection. Form.
THE WITNESS: I'm aware of a letter that's dated December 17, 2008, that says: If you do what you say you would do, we will --

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that should -- we find the corrective actions which you've propose. Once they're fully implemented, they should adequately address the observations made.
BY MR. JESSEE:
Q. Okay. Are you aware of any follow-up correspondence beyond that?
A. That's the letter that I'm aware of.
Q. Let's talk about the Ventralex labeling. And this -- I take it your Ventralex labeling opinions are not limited to the large Ventralex.
And the -- the issues we've just been talking about, the buckling, that's limited to the large Ventralex, correct?
A. I'm -- I'm --
MS. STOKES: Objection. Form.
THE WITNESS: That's a question you're going to have to do slower. I'm sorry. I just --
BY MR. JESSEE:
Q. The issue --

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A. I mean I'm not sure I -- I'm -- it's -- it's associated with large; it's nonassociated with large.
Q. Right.
The -- the issue --
A. I'm not trying to --
Q. -- with buckling that we were just talking about, that's -- and it -- according to your report, you say the large Ventralex is what the title says, Ventralex large?
A. That's correct.
Q. Okay. And then -- so we're not talking about -- when we're talking about that issue is about the design controls; we're not talking about the other size Ventralexes, right?
MS. STOKES: Objection. Form. Mischaracterizes.
THE WITNESS: Sir, because there's a -- there was a limited -- let me make just sure I understand.
Because there was a limited amount

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of time that I -- you know, and multiple devices, it's my understanding that the bellwether involved the large Ventralex, so I looked at the large Ventralex.

BY MR. JESSEE:

Q. Okay. Do you know if the bellwether cases involve any other Ventralex?

A. I -- I --

MS. STOKES: Objection. Form.

THE WITNESS: If I'm -- the answer is I'm only aware that it involves large Ventralex. I mean so that's why I focused there.

BY MR. JESSEE:

Q. Would it be fair to say, with regard to the large Ventralex design, it's your opinions you have in here that your criticisms of -- are of the testing and -- and compliance with design controls as opposed to what different designs should have been used?

MS. STOKES: Objection. Form.

THE WITNESS: Sorry. I don't

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understand the question.

BY MR. JESSEE:

Q. Are you offering opinion as to a different design Bard should have used for the Ventralex large?

MS. STOKES: Objection. Form.

THE WITNESS: No, I don't think I'm going to -- it's -- I'm not going to say what they should have used. I'm just going to say when you make -- when they made the switch to the 0.030 and they changed those characteristics and the diameter of the ring. I'm -- I'm going to say they should have tested that.

I think there was some -- I mean I'm aware that physician -- there was the issue of dual rings. And there's some e-mail correspondence saying that would require a new 510(k), and that would add time. And there was a reluctance on the -- on the part of the company to do that.

But I am not going to say that the

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answer -- I'm not going to testify that they should have gone to dual ring. But I'm aware that that was in -- that was one of -- one of the considerations.

Q. The -- is there -- for the Ventralex IFU opinions you have in here, is there a particular warning you think --

A. That's the Ventralex --

Q. IFU.

A. Right. So show me the I -- Ventralex IFU opinion I have here.

Q. Sure. It is in your section -- well, I -- I'll ask you.

Do you have Ventralex IFU opinions?

A. I have --

MS. STOKES: Objection. Form. Vague.

THE WITNESS: Again, it's a -- it's a -- it's a broad question. I'd have to go through the -- the report.

But I mean, as I understand my Ventralex section, it was a failure to assure

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adequate testing and design controls. And also on the Ventralex, the issue similarly of adequate design controls to assure testing and of the higher infection to where I do get to the IFU.

And I think this is maybe -- you're referring -- there's two paragraphs we looked at earlier where I said specifically, if there is evidence of a higher infection rate, then the IFU should have warned.

So I think that probably is the quote --

MR. JESSEE: Okay.

THE WITNESS: -- for Ventralex IFU.

BY MR. JESSEE:

Q. And that -- so you're not --

A. But -- but -- but I -- but -- but that is conditioned. I'm not going -- I'm saying that is was noticed. They should have tested. They should have seen whether there was high rate. And if, in fact, there was a higher rate, then it should have been warned

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about.
Q. Okay. Thank you for clarifying that.
PerFix Plug -- since we're running low on time, we're going to go through these products.
A. My favorite.
Q. And the -- have you -- you've reviewed the -- you reviewed the FDA's review memorandum for the Marlex mesh dart in the --
A. I studied the dart extensively. I'm not sure -- the record is not -- I will tell you your -- your -- your discovery database in the early 19 -- going back to the 1990s is limited. So I -- I had some problems finding some information on the dart, if my memory serves me right.
Q. Do you have any criticisms of the dart?
MS. STOKES: Objection. Form.
THE WITNESS: I'm going issue no opinions on the dart. I -- I issue no opinions

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on the dart.
BY MR. JESSEE:
Q. Okay. And that's the one we talked about was cleared while you were FDA commissioner, right?
A. Correct.
Q. And that's the one that's -- it's polypropylene, correct?
A. Yeah. It's two layers rather than three. It's the mushroom cap. It doesn't have the needle. It's not three layers. It's -- it doesn't have as much mesh.
Q. Okay. And I'm going to just show you -- do you have the PerFix Plug IFU --
A. Yeah. It's --
Q. -- with you?
A. Oh, I thought you wanted the PerFix Plug.
Q. No. Just the IFU.
A. Yeah. I should have the -- I have the technical file.
MR. JESSEE: I'm going to just go

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ahead and mark it as 32.
Unfortunately, I only have one copy of this.
(Deposition Exhibit 32 was marked for identification.)
THE WITNESS: Can I share with counsel?
MR. JESSEE: That's a good idea.
BY MR. JESSEE:
Q. And if -- as I understand your report, your criticism is that a -- the PerFix Plug IFU does not warn of chronic pain or of migration?
MS. STOKES: Objection. Form.
THE WITNESS: Correct.
BY MR. JESSEE:
Q. How do you define "chronic pain"?
MS. STOKES: Objection. Form.
THE WITNESS: It's -- I feel like I'm back in opioid land.
MR. JESSEE: That's not good.
THE WITNESS: I just -- I mean so

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there are -- there are a host of different definition by the different societies on chronic pain. I think that -- for the purposes of this device, I think it needs to be -- I think it -- it needs to be distinguished.
I mean there is pain that is usually associated with surgery that is acute that revolves. And I think, when one uses the word "pain" in surgical procedures, that there's going to be a pain that's going to -- to resolve.
I think chronic pain is distinguished from the acute surgical pain where the -- the usual healing period is over -- I'm not -- don't want to use the exact same terms as mesothelioization. But -- and yet there's chronic pain beyond that acute surgical healing period.
BY MR. JESSEE:
Q. Is there a particular amount of days that you would consider to be chronic pain?
MS. STOKES: Objection. Form.

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THE WITNESS: I think it's pain past the acute surgical period.
BY MR. JESSEE:
Q. Do you -- so you can't put a particular date?
A. I mean I can. There's different -- there -- the -- the -- again, I would define it as pain that doesn't resolve in the acute surgical period.
Q. Okay. And in the different sources, you're talking about there's different -- how long it is, there's going to be different numbers in there, right?
MS. STOKES: Objection.
THE WITNESS: I'm sorry?
BY MR. JESSEE:
Q. Differing numbers in the different sources you were talking about in --
A. Yeah. I mean I -- there are -- I mean I've -- I've lived this. But again, I think in the surgical context, I think the best definition of chronic pain is pain that remains

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past the acute surgical period.
Q. How do you define migration in the -- in context of your opinions in the PerFix Plug?
A. The device is not in the right place.
Q. The -- let's look at the IFUs for the PerFix Plugs, the adverse events -- adverse reactions section.
A. I mean there's also this issue of -- this is not the same at dart. I mean it -- and there's issues on substantial equivalence. I just want to --
MR. JESSEE: Okay. Well, let's go ahead -- we'll mark this then while we're -- while you're going to the adverse reaction. We're still okay with it. Adverse reaction.
THE WITNESS: Great. I -- I --
MR. JESSEE: This is going to be 33. And this will be the -- the mesh dart FOIA 510(k).
(Deposition Exhibit 33 was marked

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for identification.)
THE WITNESS: Right. Can you do me a favor and just tell me what -- the adverse reactions. I have the Russian version here.
BY MR. JESSEE:
Q. Yeah. It's --
A. Which page?
Q. I'll -- I'll --
A. The -- the Russian I'm not great at.
Q. Yeah. I'll -- I'll tell you what. And I'll just represent to you they have in here -- because I don't have the extra copy -- the -- one of the adverse reactions listed is extrusion.
Is that -- I mean is that -- do you have any reason to believe that that's not accurate?
MS. STOKES: Objection. Form.
THE WITNESS: Whether it is not -- I'm sorry. What's the question?
BY MR. JESSEE:
Q. No. Whether an -- one of the

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adverse reactions listed is extrusion?
MS. STOKES: Objection. Form.
THE WITNESS: I'm -- I'll take your -- I'll take your --
MR. JESSEE: Okay.
THE WITNESS: -- representation.
BY MR. JESSEE:
Q. What -- what does extrusion mean in the inguinal hernia repair context?
A. Extrusion usually means that it's pushed outside.
Q. Okay.
A. It's pushed out -- it's pushed outside of it's canal.
Q. The -- would you agree that the IFUs for PerFix -- and I don't know if you have a better copy. I apologize. I know that's small there to try to read -- talk about, though, how the physician should pick the right size and make sure it's fixated, the device?
A. I have to look specifically. I'm -- I -- I don't have -- I mean I -- at some points

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I looked at the fixation requirement on lingual. I don't want to make any representations without having these out in front of me.

Q. Okay. The --

MR. JESSEE: Did I give you a copy of that? Yeah.

MS. STOKES: Yes.

BY MR. JESSEE:

Q. Exhibit 33 is the FOIA file for the Marlex mesh dart. And --

A. Does this have an -- does this have an MPPE?

Is this -- is this from the database?

Q. I don't -- these are one of the publicly available things. I'm not sure if it's in the database or not.

A. So it wasn't produced.

Q. I -- I can't tell you.

A. It doesn't have a -- it doesn't have a Bates number.

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Q. Do you know -- do you recall reviewing the -- review memorandum from the Bard Marlex mesh?

A. I -- I looked for this stuff in the database. And I don't remember being able to see it. Let's me just -- let me just -- keep on asking me, and I'll answer your --

Q. Sure.

A. Yeah. So I did -- I was able to finally --

Q. You -- you under --

A. I have the 1992 --

Q. Okay. And I -- I know you talk about the note to file that was submitted.

A. On PerFix.

Q. On PerFix, right?

A. Right.

Q. And with that note to file, there were submitted several clinical studies, correct?

MS. STOKES: Objection. Form. Vague.

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THE WITNESS: So with that -- so let me just answer that question. So --

BY MR. JESSEE:

Q. And actually, you know what? It might be easier, that document I gave you, if we were to look at -- and it's double-sided.

A. Hold on one second. Well, I have the letter file. And I have all --

Q. Okay.

A. -- the testing that was done.

So what testing did you say?

Q. Well, in the -- in the letter to the file, do you see the executive summary --

A. I have --

Q. -- section?

A. I have it right in front of me.

Q. Okay. And you see at the footnote at the bottom of the page it talks about: Formally known as Marlex mesh. Marlex is a trademark of Phillips Petroleum"?

A. Correct.

Q. And the -- right about that picture

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where I just read, the footnote says -- talking about the Bard mesh and mesh dart. And it says: Since that time, the safety and effectiveness of the PerFix --

A. Do -- only -- my only complaint to your -- is you got to point me where I'm going.

MS. STOKES: Yeah. What page are you on?

MR. JESSEE: I am on the -- the -- in the executive summary there.

THE WITNESS: Just which paragraph?

MS. STOKES: On your document, which page are you on?

MR. JESSEE: With the -- I don't think there's numbering.

THE WITNESS: I'm only Page 2.

BY MR. JESSEE:

Q. Let me just have a -- I'll do this differently.

Can you just explain to me in your own words what your criticisms of the note to file are?

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MS. STOKES: Objection. Form.
THE WITNESS: My -- my real criticism of this is Bard changed the characteristics of the device in two ways. One, it increased the amount of -- of mesh to three layers. And if you go feel it, you can -- you know, this has -- you know, this hasn't pointed -- has some kind of needle stitch here.
And it certainly could raise questions -- more mesh in that space, differing configuration, a pointed needle stitch, that could -- could raise safety questions.
So again, it's supposed to be the same as the dart, but it's not the same as the dart.
Q. Did the FDA, when Bard submitted the note to file, indicate -- give any indication to Bard that they thought it was -- Bard's actions were inappropriate?
MS. STOKES: Objection. Form.
THE WITNESS: It was the -- well,

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it -- it did say that you -- you should go back and submit this stuff. We can't approve the like without having this note to the file and this documentation.
It -- so it was inappropriate not to have the documentation on the -- the -- this PerFix was evaluated. It couldn't move to light. The FDA was very clear on that.
BY MR. JESSEE:
Q. And the FDA though didn't require them to file a 510(k) for the PerFix Plug, correct?
A. No. They had filed a 510(k) that was a lighter mesh, right, which -- and the FDA -- this was now how many -- this is, what, how many years later, a decade-plus. I forget exactly. 2003. Light was when? I mean 2000 -- I -- I forget exactly what was the date.
Q. I mean that's -- that's fine. We're --
A. Was about -- about a decade later.

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And so FDA said, "Hey, we can't go ahead and look at the light without looking at the -- having a regulatory record here."
Q. Have you -- but they never acquired a 510(k) for the -- can we agree on the -- for the PerFix -- regular PerFix -- they never acquired -- they -- the -- PerFix 510(k)?
MS. STOKES: Objection. Form.
THE WITNESS: That -- that -- that -- correct. They let Bard get away with -- because it was already -- it had already been a decade with it. You know, it was one of those questions.
BY MR. JESSEE:
Q. And the -- the FDA has never required either premarket or postmarket clinical studies for the PerFix, right.
A. It's not -- there's been no 522 or --
Q. And that's true for all the hernia mesh devices we've talked about today, right?
MS. STOKES: Objection. Form.

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THE WITNESS: Not yet.
BY MR. JESSEE:
Q. Right.
They -- as we sit here today, they haven't -- you haven't seen any indication that they're going to either, have you?
MS. STOKES: Objection. Form.
THE WITNESS: The -- that's correct. But it's -- you know, we -- we've been through this with urogynecological meshes and we -- there are -- when there are issues and when FDA focuses.
But you are correct. There is no 522 order. And I don't see a FDA focus on these devices at this moment in time.
BY MR. JESSEE:
Q. And why do you say that?
A. It's what I see from the record.
Q. The -- have you reviewed labeling for any other plug mesh devices?
MS. STOKES: Objection. Form.
THE WITNESS: Only dart and PerFix.

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BY MR. JESSEE:
Q. Okay. That's -- when you're saying "dart," you mean the Marlex mesh dart?
A. Yes, sir.
Q. Okay. The 3DMax, the -- your opinion there, I believe, is --
A. Similar.
Q. Right.
In the -- in that you say they admitted certain warnings from the labeling and they --
A. It's chronic pain.
Q. Chronic pain is that what --
A. Same thing.
Q. Okay. And you understand that -- that's -- is that the extent of your -- and that's what I see in your report in there, the extent of your criticisms of the 3DMax?
MS. STOKES: Objection. Form.
THE WITNESS: Yeah. I think that's -- yeah. I mean I think that there -- the issue is simply the complaints and the -- the

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concerns about long-term pain.
BY MR. JESSEE:
Q. Okay. And so -- again, with -- with the 3DMax Light with PerFix Plug -- well, let me just strike that.
With the 3DMax, the -- the -- Bard did submit the IFU to the FDA, right?
MS. STOKES: Objection. Form.
THE WITNESS: That was before my time, I believe -- let's see. What was the date of 3DMax?
Can I have my general -- can I please have my general sheet. Let me just see.
Yeah. So that is a -- that's a 1979. I don't have the -- do I have -- I'm not sure I have the 510(k). I -- I'll answer that in a second.
Yep. I actually -- I have a tubular 510(k). I can go through it and tell you what they submitted.
BY MR. JESSEE:
Q. I don't think we have time for that,

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unfortunately.
The -- you know, I -- we've -- we've talked about I think the -- have we talked about your criticisms as they relate to the four devices: the 3DMAX, the PerFix Plug, the Ventralex, and the Ventralight ST?
MS. STOKES: Objection. Form.
THE WITNESS: The two -- there's -- there's a Ventralex with PET and a Ventralex with PDO. And there's a shift.
Did we talk about -- I think we talked about --
BY MR. JESSEE:
Q. Well, do you have any criticisms of the shift to the PDO ring?
Because I didn't see them in your report.
A. I think that the issues with -- certainly with infection -- the -- the -- anything that -- anything that applied on the higher rate of infection would apply to the PDO ring as well as the PET.

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Q. Okay. And you understand though that the -- so your opinions about infection with respect to the Ventralex relate to ePTFE, not some other aspect of the device?
MS. STOKES: Objection. Form.
THE WITNESS: I'm not sure I fully understand the question. I'm sorry.
BY MR. JESSEE:
Q. Well, you're obviously -- if you're saying that your opinions on infection are applied to whether it's the PDO ring or the PET ring, obviously the ring is not any -- not any issue -- not related to the infection issue, right?
MS. STOKES: Objection. Form.
THE WITNESS: Yeah. I'm not sure you -- I mean you're -- you're correct --
MR. JESSEE: Maybe I can ask a better question.
THE WITNESS: You're correct, in part, that the things are connected. So I just don't want to --

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BY MR. JESSEE:
Q. Okay. And your opinions on this ground are really about the design controls in place, right?
MS. STOKES: Objection. Form.
THE WITNESS: Fair.
BY MR. JESSEE:
Q. Okay. But -- and there's actually different though -- does -- there a different design validation testing done for the PDO and PET, correct?
A. I believe that -- that's correct.
I don't see infection -- the -- the infect -- evaluation of infection, susceptibility and holding the bacteria and clearance of bacteria in either.
Q. Okay. And the -- have you reviewed the design history file for the PDO?
A. I'd have to go back and check. I think I have the design history file.
Q. Okay. Do you know what animal testing was done on that PDO ring?

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MS. STOKES: Objection. Form. Vague.
THE WITNESS: I think you've -- I think you've -- I don't think -- I think you've stumped me. I mean I -- I'd have to -- I'd have to go pull and sort it out.
I have all -- I have all the testing -- I mean I have all the testing that was done on Ventralex over the years. But I would have to sort out PDO and PET.
BY MR. JESSEE:
Q. Would you agree that it's not -- it's not a good thing for medical device manufacturers to bring in third-party companies to do audits?
MS. STOKES: Objection. Form.
THE WITNESS: I was fine until you have a negative in there. So you lost me to -- can you do it in the -- without a negative there.
BY MR. JESSEE:
Q. Would you agree that it's

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appropriate for a medical device company to bring in third-party companies or organizations to do audits of their quality systems?
A. Sure.
Q. Would you agree that it would be unreasonable for a medical device manufacturer to not consider FDA regulations and standard in bringing a device to market?
MS. STOKES: Objection. Form.
THE WITNESS: Do it -- do it without a negative. I'm sorry. I just want to make sure. You have "unreasonable" and then "not consider." And my brain is not going process both words in the same sentence.
BY MR. JESSEE:
Q. A -- a reasonable medical device manufacturer would consider FDA standards and regulations in bringing a medical device to market, correct?
MS. STOKES: Objection. Form.
THE WITNESS: Well said.
BY MR. JESSEE:

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Q. Okay. And that's true whether it's through the 510(k) process or the PMA process, correct?
A. Of course.
MS. STOKES: Objection. Form.
BY MR. JESSEE:
Q. And it's be unreasonable for a manufacturer not to consider FDA standards in regulations, right?
A. Absolutely.
MS. STOKES: Objection. Form.
THE WITNESS: I mean -- again, absolutely. But the -- but the -- and just add to that and -- and ultimate patient safety, and we will -- I'm very happy to agree with you.
BY MR. JESSEE:
Q. Okay. And that -- we can agree. I wasn't saying that was the only thing, but that's certainly one of the things --
A. But -- but -- right. But the -- the real issue is those standards as it relates to patient safety.

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Q. Okay. In the -- you've testified at trials about the FDA's review of medical devices before, right?
A. I have.
Q. And that's including 5 -- trials involving 510(k) devices?
A. I'm sure.
Q. And with your experience, you can -- you're -- you've been able to explain to a jury about the 510(k) process?
MS. STOKES: Objection. Form.
THE WITNESS: I think so. Yes.
BY MR. JESSEE:
Q. And it's --
A. Yes. And I'm not trying to understand your -- your question, what --
Q. Did you feel like you had any difficulty explaining the concept of 510(k) to a jury?
MS. STOKES: Objection. Form.
THE WITNESS: I -- I -- if you give me a few minutes, I can explain it. I'm -- to

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explain it under rapid fire -- we could -- I mean maybe not. But I'm sure you and I could do a module that we can explain it.
MR. JESSEE: Okay.
THE WITNESS: I mean -- but it -- it -- I mean it takes a couple of minutes to explain it. It's not in a -- you know, it's not something that someone's going to understand.
But in -- in -- in five minutes, I think I can explain it.
BY MR. JESSEE:
Q. And, Dr. Kessler, again, I've tried to be thorough today. I appreciate your -- your patience in doing that.
Any other opinions that either aren't in the body of your report or that we haven't discussed today about the Bard's -- about Bard's hernia mesh products?
A. I think -- I think we've --
MS. STOKES: Objection. Form.
THE WITNESS: You know, I -- I think

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we've dealt with anything -- I think that we dealt earlier with some of the issues with regard to the -- Dr. Tillman's comments on the MSDS and my opinions or my -- my views, whatever, of that. And I put that on the record.
Save for that, I appreciate very much your --
MR. JESSEE: All right. Thank you, Doctor. That's all the questions I have for you.
THE WITNESS: Thank you very much, sir. I appreciate the -- the kindness.
MS. STOKES: Let's take a quick break.
MR. JESSEE: Well, and I should say pending questions from your counsel.
THE VIDEOGRAPHER: We are going off the record.
The time is 4:41.
(A short recess was taken.)
THE VIDEOGRAPHER: We are going back

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on the record.
The time is 4:57.
EXAMINATION BY COUNSEL FOR PLAINTIFFS
BY MS. STOKES:
Q. Dr. Kessler, I just want to make sure that the record is clear.
What is your opinion on the MSDS?
MR. JESSEE: Objection to the form.
THE WITNESS: Gerard, can just I trouble you for my MSDS sheets just so I can have those in front of me.
So there's -- there's actually several different sheets. There -- there were early sheets. There were 2004 sheets of Phillips -- I'm not going to pronounce it right -- Sumika. There are -- I think I have -- I just get -- and I'm not going to pronounce this one also -- Lyondellbasell.
So there are a number of different suppliers counsel asked me earlier about which was used at which points in time. And that's answered in the interrogatory questions.

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Because the -- the -- the FDA, through ISO 10993, Part 18, concurs with the ISO standard that each -- each material be well characterized chemically, and because there is in the technical file and in the MSDS issues with regard to degradation of the material, right? I mean in these MSDS -- certainly in -- in -- in -- as I read it, there is -- and there's also a warning -- I believe Marlex -- they're -- they're -- they're stated a little differently. Do not use -- the -- the -- the Marlex says: Do not use Phillips Sumika polypropylene material in medical applications.

And it -- it -- goes on. And I think the Lyondell -- I'm -- the -- the -- the other MDS -- the Pro-fax MDS I think states it a little differently and says: Don't use -- may not be used in U.S. -- This product may not be used in the manufacture any of the following without written prior approval for U.S. Class I or Class II.

I mean, again, I'm -- I'm

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summarizing.

But because of that issue of oxidative damages as part of the chemical characterization, that could present a potential safety hazard and, therefore, should be warned about.

MS. STOKES: All right. Thank you.

MR. JESSEE: And I just want to note on the record that it's Bard's position that the -- this issue of the MSDS and the testimony that was just given was not in Dr. Kessler's expert report; it was not in his errata sheet that was served on us yesterday. We had no notice whatsoever of this opinions regarding MSDS, degradation, oxidation, raw materials that was just testified to.

And we object and think it's improper, those opinions. To the extent Dr. Kessler is allowed to give those opinions, we reserve the right to depose him on those issues at a time where we will -- as today, we don't have the MSDS documents. We don't have the

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testimony. We -- as I said, we had no notice to do -- conduct a meaningful cross-examination of those opinions.

And so we would reserve the right -- to the extent the opinions are allowed, which we obviously suggest they should not be, we reserve the right to conduct an additional deposition on those opinions.

MS. STOKES: Obviously plaintiffs disagree. But we can take it up with the Court.

MR. JESSEE: Oh, and let's -- I'm sorry. Just real fast then.

Doctor, we've discussed the -- about the -- the documents you brought with us. And you're going to make your best faith effort, after they are copied, to keep them until this litigation's over, right?

THE WITNESS: Yeah. Absolutely. They just keep me -- I will -- I promise to try -- I will keep them in my garage as soon as I have them and try to keep them in good

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storage.

If you guys can -- if you can keep me abreast of when this litigation is over. Sometimes that's a nebulous term.

MR. JESSEE: You're asking the wrong person.

THE WITNESS: I -- I -- I -- you know --

MR. JESSEE: Yeah, that's --

THE WITNESS: What that point in time is -- let's agree that I'm happy to keep them -- pick a -- pick a -- pick a -- a fair period of time.

You want three years? What do you want?

MR. JESSEE: Whatever. We can figure that out.

THE WITNESS: Yeah. But just so you understand "litigation over" is a --

MR. JESSEE: Yeah.

THE WITNESS: -- little vague.

MR. JESSEE: I --

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THE WITNESS: I mean certainly, if I'm involved -- I will keep them as long as I'm involved.
MR. JESSEE: Okay. And then, Ms. Stokes, we are agreeable that you're -- you'll have -- send those exhibits that have been here, make copies, and just make representation that you're not going to make any changes to them?
MS. STOKES: Yeah. We will instruct -- we will be very careful to instruct the vendor not to make any changes --
MR. JESSEE: Okay. What --
MS. STOKES: -- and keep them in order.
MR. JESSEE: Great. And that's agreeable for us.
The one quick issue then on the exhibits. I accidentally labeled two exhibits 28. So what we're going to do is label device labeling guidance exhibit, which was the first one marked Exhibit 28 is 28A. And this is from

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1991.
And then the Ventralight ST instructions for use we are going to label as 28B.
That's all I have.
MS. STOKES: All right.
MR. JESSEE: Okay.
THE VIDEOGRAPHER: We are off the record at 5:03 p.m.
And this concludes today's testimony given by Dr. David A. Kessler.
The total number of Media Units used was five and will be retained by Veritext Legal Solutions.
(Whereupon, the proceeding was concluded at 5:03 p.m.)

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CERTIFICATE OF NOTARY PUBLIC

I, Bonnie L. Russo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand and thereafter reduced to computerized transcription under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

Bonnie L. Russo
Notary Public in and for
the District of Columbia
My Commission expires: June 30, 2020

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ACKNOWLEDGMENT OF DEPONENT

I, DAVID A. KESSLER, M.D. do hereby certify that I have read the foregoing transcript of my testimony taken on 1/31/20, and further certify that it is a true and accurate record of my testimony (with the exception of the corrections listed below):

Page	Line	Correction
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____
DAVID A. KESSLER, M.D.

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____DAY OF ________________, 2020.

________________ ________________
(NOTARY PUBLIC) MY COMMISSION EXPIRES: